

103
Y 4. W 36:103-96

ISSUES RELATING TO MEDICATION ERRORS

Issues Relating to Medication Error...

HEARING

BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON WAYS AND MEANS
HOUSE OF REPRESENTATIVES
ONE HUNDRED THIRD CONGRESS

SECOND SESSION

SEPTEMBER 20, 1994

Serial 103-96

Printed for the use of the Committee on Ways and Means



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ISSUES RELATING TO MEDICATION ERRORS

TUESDAY, SEPTEMBER 20, 1994

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:06 a.m., in room B-318, Rayburn House Office Building, Hon. Fortney Pete Stark (chairman of the subcommittee) presiding.

[The press release announcing the hearing follows:]

FOR IMMEDIATE RELEASE
THURSDAY, SEPTEMBER 15, 1994

PRESS RELEASE #29
SUBCOMMITTEE ON HEALTH
COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES
1102 LONGWORTH HOUSE OFFICE BLDG.
WASHINGTON, D.C. 20515
TELEPHONE: (202) 225-7785

THE HONORABLE PETE STARK (D., CALIF.), CHAIRMAN,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON WAYS AND MEANS, U.S. HOUSE OF REPRESENTATIVES,
ANNOUNCES A HEARING ON ISSUES RELATING TO MEDICATION ERRORS

The Honorable Pete Stark (D., Calif.), Chairman, Subcommittee on Health, Committee on Ways and Means, U.S. House of Representatives, announced today that the Subcommittee will hold a hearing on issues relating to medication errors. The hearing will be held on Tuesday, September 20, 1994, beginning at 10:00 a.m., in room B-318 Rayburn House Office Building.

In announcing the hearing, Chairman Stark stated: "Every day patients are killed or injured because they are given either the wrong medication or the wrong dose of medication. We need to improve our efforts in monitoring medication errors and to educate and inform health professionals of mishaps that can take place when prescribing, dispensing, and administering medications."

Oral testimony will be heard from invited witnesses only. However, any individual or organization may submit a written statement for consideration by the Subcommittee and for inclusion in the printed record of the hearing.

BACKGROUND:

Medication errors can occur in the prescribing, transcribing, communication, dispensing, or administration of medications. Moreover, patients taking marketed drugs in conjunction with other drugs may experience interactions not revealed during the Food and Drug Administration (FDA) clinical trial phase.

The United States Pharmacopoeial Convention (USP) and the Institute for Safe Medication Practices collect reports on medication errors and study them in an effort to provide feedback to practitioners, the FDA, and product manufacturers. Reports are voluntary and are most often received by telephone or submission of a standard form. USP received 568 such reports between August 1991 and April 1993.

Only two States now require reporting of medication errors: New York has a mandatory program for hospitals, and North Carolina has a required reporting system for its pharmacies.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

For those who wish to file a written statement for the printed record of the hearing, six (6) copies are required and must be submitted by the close of business on Tuesday, October 4, 1994, to Janice Mays, Chief Counsel and Staff Director, Committee on Way and Means, U.S. House of Representatives, 1102 Longworth House Office Building, Washington, D.C. 20515. An additional supply of statements may be furnished for distribution to the press and public if supplied to the Subcommittee office, 1114 Longworth House Office Building, before the hearing begins.

FORMATTING REQUIREMENTS:

Each statement presented for printing to the Committee by a witness, any written statement or exhibit submitted for the printed record, or any written comments in response to a request for written comments must conform to the guidelines listed below. Any statement or exhibit not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All statements and any accompanying exhibits for printing must be typed in single space on legal-size paper and may not exceed a total of 10 pages.
2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.
3. Statements must contain the name and capacity in which the witness will appear or, for written comments, the name and capacity of the person submitting the statement, as well as any clients or persons, or any organization for whom the witness appears or for whom the statement is submitted.
4. A supplemental sheet must accompany each statement listing the name, full address, a telephone number where the witness or the designated representative may be reached and a topical outline or summary of the comments and recommendations in the full statement. This supplemental sheet will not be included in the printed record.

* * * * *

Chairman STARK. Good morning. We will wait to see whether anyone wishes to proceed with an opening statement. We may suspend the hearing for a moment or two.

The Subcommittee on Health is meeting today on issues relating to medication errors. These errors could occur in the prescribing, the transcribing, or dispensing of medications. The errors involve administering the wrong drugs, delivering and improper dosage or prescribing an inappropriate spectrum of medication.

It is not uncommon for patients to be seriously injured as a result of these errors.

Many hospitals have established mechanisms to monitor medication errors, such as incidence reports; however, they typically remain within the institutions and are not available to the public. As a result, health care professionals rarely have the opportunity to learn about the mistakes that pertain to medications in order to avoid making mistakes themselves or learning from their mistakes.

Currently the U.S. Pharmacopeial Convention and the Institute for Safe Medication Practices operate a voluntary reporting system for medication errors. Under this program, these organizations sought data on medication errors and studied them in an effort to provide feedback to practitioners, the FDA, and product manufacturers.

This hearing, we hope, will provide us with an opportunity to discuss the problem of medication errors, to evaluate the adequacy of reporting systems, and to suggest ways to improve the monitoring and control of medication errors.

I look forward to the testimony of our witnesses this morning, and I would like to suspend briefly while I check with the staff as to the protocol before we proceed.

[Recess.]

Chairman STARK. We will hear first from our colleague, Bill Coyne, of Pittsburgh. He has introduced legislation that would require reporting of deaths resulting from medication errors.

He has acted persistently during the course of the year to focus attention on this problem. And I think he thought we were going to be too late for health reform. And here it is today that we are reviewing a topic that is left to discuss. So patience is a virtue and has its own rewards.

After we hear from Congressman Coyne, there will be a panel—there will be two panels. I will ask the members of the panels to summarize their testimony, if they would, in approximately 5 minutes each to allow us to inquire of them individually. And I will ask Congressman Coyne to join us after his testimony.

We will suspend for a moment. We will suspend for approximately 5 minutes.

[Recess.]

Chairman STARK. I will call Mr. Coyne and hear his testimony at this point.

Welcome to the subcommittee, Bill, and we will let you proceed to enlighten me and the staff, however you are comfortable.

**STATEMENT OF HON. WILLIAM J. COYNE, A REPRESENTATIVE
IN CONGRESS FROM THE STATE OF PENNSYLVANIA**

Mr. COYNE. First of all, Mr. Chairman, I want to thank you for the opportunity to testify here today and for your holding these hearings to examine the issue of medication errors and how best to respond to the tragic deaths that are associated with some of the errors that are committed.

As Americans, we hear daily how we are the most advanced health care system in the world. This stellar medical system includes technology that is able to diagnose diseases before they develop and cutting-edge surgery that reconstructs and replaces vital organs. The system also includes a wide variety of medications and devices used to treat and to cure illnesses. These sophisticated technologies and the wide ability and availability of medications and devices also unfortunately increase the chances for mistakes. Sometimes these errors have little health consequences; sometimes they cause permanent damage to an individual's well-being, and sometimes they are fatal.

Under our present medical system, if a health care practitioner accidentally prescribes, dispenses, or administers an inaccurate dose of a drug or confuses the labels of two drugs and mismedicates a patient, there is no required reporting system in most cases for practitioners to share the incident. Ultimately since there is no mandatory reporting system, these unfortunate occurrences are repeatedly causing permanent health problems for productive people and sometimes killing others.

In October 1993, the Pittsburgh Post-Gazette published a series of articles on this particular topic, written by Steven Twedt. It contains some disturbing statistics in the area that I mention. He reported that a study of 250 hospital pharmacists across the country estimated that there were 16,000 medication errors in their institutions in 1992 and 106 of them caused patient deaths.

After reading the Post-Gazette's series on this topic and after reviewing extensive industry data, I have concluded that the present system for monitoring medication errors needs to be improved.

A voluntary reporting program established in 1992 has tracked over 600 mishaps that have occurred in a variety of health care facilities. These reports of medication errors that are available illustrate that medication errors are not confined to one setting and that the same faults are often repeated. Currently there are no substantive figures to indicate the number of incidents which may be occurring. The only way medical boards are alerted to problems is if consumers or health personnel voluntarily report them.

Experts in the field cite national estimates that 1 in 3,000 prescriptions are indeed written wrong. One such authority put it in perspective: If there are 4 billion prescriptions a year, 1 error in 3,000 is "a lot of errors."

Only two States require reporting medication errors. New York has a mandatory program for hospitals, and North Carolina has a required reports system for its pharmacies. Unfortunately, mistakes that may be reported in New York or North Carolina could most likely be occurring in other parts of the country. Regretfully, we have no certain way of knowing this. That is why it is impor-

tant to establish a structure to interface both on State and Federal levels.

In 1992, the Institute for Safe Medication Practices established the medication error reporting program, MER. This voluntary system is coordinated by the U.S. Pharmacopeia, the organization that sets drug standards and publishes drug information.

Unfortunately, this voluntary system does not provide patients or health care professionals with any certainty that all medication errors are being reviewed at the national level. As one of the founders of the MER program recently noted:

We know we do not get a very large percentage of the actual incidents, because it is not required. We need to maintain and expand upon the voluntary MER program. This can be done by requiring all health care entities to report deaths caused from medication errors to the FDA. The U.S. Pharmacopeia and FDA already collaborate to help address faults that health professionals elect to share.

This effort is catching some of the medication errors, but we need to bolster that effort. Second and perhaps most importantly, to protect the public health and welfare, we must ensure that this information is disseminated to other health care providers to educate them and minimize unnecessary risks.

With this in mind, I have developed H.R. 3632, the Safe Medications Act. This bill will, No. 1, establish a system that will address misinterpretation, misreading and misdiagnosing drugs by requiring health care institutions to report deaths caused by medication errors to one central entity.

No. 2, the Safe Medications Act will require the FDA to review this information and share it with other providers who prescribe, dispense, and administer prescription drugs.

No. 3, H.R. 3632 will protect the confidentiality of the individuals and institutions involved, so that honest oversights can be addressed without assigning liability.

This bill authorizes the necessary appropriations for this data bank, and I have asked the Congressional Budget Office to provide a cost estimate on it.

Mr. Chairman, today medication errors occur that often result in death. Most times, these are honest mistakes made by otherwise competent providers. We need to establish a neutral educational system that will help medical personnel who prescribe, administer, and dispense medication and perhaps cause a fatal accident to share their experience anonymously with their peers.

Health professionals have concluded that learning of their colleagues' experiences is helpful for practicing better medicine and preventing recurring problems in the system. Educating health care professionals more effectively about real-world cases of medication errors serves the same purpose. With a greater awareness of potential problems, safeguards can be instituted to avoid them. The result would be to promote better patient care, and this is something that we can all support.

I look forward to working with all the groups involved with the effort to construct the most effective system possible, so that we can reduce errors and improve America's health.

Thank you very much.

[The prepared statement and attachment follow:]

TESTIMONY OF REPRESENTATIVE WILLIAM J. COYNE

SEPTEMBER 20, 1994

WAYS AND MEANS HEALTH SUBCOMMITTEE

Thank you Mr. Chairman. I am pleased that the Subcommittee is holding this hearing to examine the issue of medication errors and how best to respond to the tragic deaths associated with some of these errors.

As Americans, we hear daily of how we have the most advanced health care in the world. This stellar medical system includes technology that is able to diagnose diseases before they develop and cutting edge surgery that reconstructs and replaces vital organs. The system also includes a wide variety of medications and devices that are used to treat and cure illnesses.

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Currently, there are no substantive figures to indicate the number of incidents which may be occurring. The only way medical boards are alerted to problems is if consumers or health personnel voluntarily report them. Experts in the field cite national estimates that indicate that one in 3,000 prescriptions are indeed wrong. One such authority put it in perspective: if

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Secondly, and perhaps most importantly, to protect the public health and welfare, we must ensure that this information is disseminated to other health care providers to educate them and minimize unnecessary risks.

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I look forward to working with all the groups involved with this effort to construct the most effective system possible so that we can reduce errors and improve America's health.

103D CONGRESS
1ST SESSION

H. R. 3632

IN THE HOUSE OF REPRESENTATIVES

Mr. COYNE introduced the following bill: which was referred to the Committee
on _____

A BILL

To require the mandatory reporting of deaths _____
_____ resulting from errors in the
prescribing, dispensing, and administration of drugs, to
allow the continuation of voluntary reporting programs,
for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE AND PURPOSE**

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “Safe Medications Act of 1993”.

1 (b) PURPOSE.—It is the purpose of this Act to have
2 the Secretary of Health and Human Services create a data
3 bank for reports of errors in the prescribing, dispensing,
4 and administration of drugs, to establish a program using
5 such data to assist in preventing such errors, and to edu-
6 cate and inform health care professionals of the deaths
7 that may occur in the course of drug therapy.

8 **SEC. 2. REPORTING.**

9 (a) IN GENERAL.—Any pharmacy, hospital, long-
10 term care facility, physician's office, or other health care
11 facility, as defined by the Secretary of Health and Human
12 Services by regulation, in which an error occurs in the pre-
13 scribing, dispensing, or administration of a drug to an in-
14 dividual which results in the individual's death shall report
15 such error and resulting death to the Secretary of Health
16 and Human Services under section 3. Such a report shall
17 be made not later than 10 working days after the date
18 of the discovery of the error resulting in such death.

19 (b) REPORT REQUIREMENTS.—Each report of an
20 error in the prescribing, dispensing, or administration of
21 a drug to an individual shall contain—

22 (1) an identification of the person making the
23 report, including the address and telephone number
24 of such person, and the name and address of the fa-
25 cility in which the error occurred,

(2) the brand names of the drugs involved, the generic names of the drugs, the manufacturers of the drugs, the labeler of the drug if different from the manufacturer, the dosage form of the drugs, the strength of the drugs, and the type and size of the containers,

(3) the lot number of the drugs, if available,

(4) a description of the error,

(5) information on the patient for whom the drug was prescribed, dispensed, or administered, including the patient's age and sex,

(6) the diagnosis for which the drug was prescribed, dispensed, or administered,

(7) the date and time the death, and

(8) when and how the error was discovered.

SEC. 3. DATA BANK.

(a) ESTABLISHMENT.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall establish a data bank to receive reports under section 2 of errors resulting in deaths.

(b) SECRETARIAL ACTION.—The Secretary shall review information reported to the data bank on an ongoing basis to determine trends relating to drugs and shall report such information to the compilers of the official compendia on an ongoing basis for consideration of revision

1 of the packaging and labeling requirements or other stand-
2 ards for drugs for dissemination of information to physi-
3 cians, pharmacists, and other health professionals involved
4 in the prescribing, dispensing, and administration of drugs
5 to patients. Such reporting of aggregate data shall be done
6 in a manner which assists such health professionals in
7 identifying and reducing patterns and incidents of inap-
8 propriate and misuse associated with certain drugs.

9 (c) CONFIDENTIALITY.— The identity of a person
10 making a report to the data bank, the deceased, or the
11 individual believed to have caused the error shall be con-
12 sidered as privileged and confidential information for pur-
13 poses of any law requiring disclosure of information.

14 (d) SHARED INFORMATION —THE SECRETARY
15 SHALL SHARE THE REPORTED INFORMATION WITH LI-
16 CENSING, ACCREDITATION, AND INSPECTION ORGANIZA-
17 TIONS FOR THEIR FOLLOWUP WITH THE APPROPRIATE
18 ORGANIZATION TO ENSURE THAT THERE HAS NOT BEEN
19 UNDERREPORTING OF MEDICATION ERRORS RELATED TO
20 DEATHS.

21 (e) ENFORCEMENT.—Whoever with false pretenses
22 reports to the data bank, requests information from the
23 data bank, or unlawfully gains access to the data bank
24 shall be fined not more than \$15,000 or imprisoned for
25 not more than 3 years, or both, except that if a person

1 commits a violation of this subsection after a conviction
2 for a violation of this subsection has become final, such
3 person shall be fined not more than \$25,000 or imprisoned
4 for not more than 3 years, or both.

5 **SEC. 4. PENALTIES.**

6 (a) **IMPOSITION OF FINE.**—Any institution that does
7 not make a report as required by section 2 shall be subject
8 to a fine of \$15,000 for each report not made. Within 60
9 days of a conviction under this subsection, a person shall
10 submit to the Secretary of Health and Human Services
11 a plan for the reporting to the data bank of drug prescrib-
12 ing, dispensing, and administration errors.

13 (b) **MANDATORY EXCLUSION FROM MEDICARE AND**
14 **STATE HEALTH CARE PROGRAMS.**—Section 1128(a) of
15 the Social Security Act (42 U.S.C. 1320a-7(a)) is amend-
16 ed by adding at the end the following new paragraph:

17 “(3) **FAILURE TO REPORT DEATHS RESULTING**
18 **FROM ERRORS IN THE PRESCRIBING, DISPENSING,**
19 **AND ADMINISTRATION OF DRUGS.**—Any individual
20 or entity that has failed to meet the requirements of
21 section 2 of the Safe Medications Act of 1993.”.

22 **SEC. 5. AUTHORIZATION.**

23 There are authorized to be appropriated to carry out
24 this Act and the amendment made by this Act such sums
25 as may be necessary.

Chairman STARK. Thank you, Bill.

The suggestion has been made that we go beyond your bill, which I think deals just with reporting mistakes that result in death, and expand that to report all serious adverse events, if that is a term of art, and caused by mismedication.

Do you have any feelings on that, making the net a little wider?

Mr. COYNE. Well, I think that would be an even larger task than just requiring the reporting of deaths associated with medication errors. And I think it would be a major undertaking—more major than just reporting the deaths for the FDA to take on at this point.

If, after legislation would be adopted—

Chairman STARK. I think we had the term “serious adverse reaction,” and I am not sure that that is a medical term that everybody would understand. But it does seem to me that coming close to getting killed is worth knowing, just because you survived, that there be some interest in adverse reactions that resulted in a month’s stay in the hospital or putting somebody into a coma or shock. He ain’t dead, but it would sound to me like that would be a serious adverse event and possibly ought to be included.

Your concern only is that it would increase the work involved or the size of the program?

Mr. COYNE. Clearly it would put a larger mandate on the FDA to be able to administer received expanded incidents aside from deaths.

Chairman STARK. If the FDA could handle it, would you—

Mr. COYNE. Well, that is something we would like to hear from the FDA.

Chairman STARK. OK.

Mr. THOMAS. Mr. Chairman—

Chairman STARK. I just had another question.

Mr. THOMAS. On that point, though, are adverse reactions currently being reported to FDA?

Chairman STARK. I do not know as there is—

Mr. THOMAS. I believe they are.

Chairman STARK. I do not know.

Mr. THOMAS. I am getting a nod “yes” from the staff. I am getting a nod “yes” out in the audience. So I guess adverse reaction is covered. Those who die from it, are an extreme adverse reaction.

Chairman STARK. But that may be in the voluntary program and not in the mandatory program.

Mr. THOMAS. I understand it is mandated by law. So we will pursue that.

Chairman STARK. That they have to report it, adverse reactions but not deaths?

Mr. THOMAS. Well, I think we will get testimony later to clear this up.

Chairman STARK. Death sounds like a pretty adverse event to me.

Mr. THOMAS. Thank you, Mr. Chairman.

Chairman STARK. Also we will hear later that it might be suggested—and this is an area in which I am not sure I am anxious to get involved—but that it might be an idea that physicians need some more education in pharmacology, and that it would be reason-

able to require that physicians meet some more—some minimal standards as a requirement before prescribing drugs.

Have you thought on that at any—

Mr. COYNE. I just happened to have a brief conversation with a representative from the Pharmacopeia, who indicates that they are making an effort to get more information into the hands of medical students, and I am sure that he is going to touch on that in his testimony later on.

Chairman STARK. Mr. Thomas.

Mr. THOMAS. Thank you, Mr. Chairman.

I think one of the things we need to do is probably make sure that we have a truly professional team as we deal with the question of medication in coordination with the doctor.

I thought coordination was one of the roles for pharmacists. It seems we need to focus on their training level of participation in the structure, rather than thinking we can go back and invest it all in medical doctors.

Mr. Coyne, I was looking for the definition section of the bill. I do not see it, and the reason I was looking for a definition section is that I do not understand the difference between an honest oversight and an error.

To me, an error could very well be an honest oversight. The language I see in the bill is "errors."

Is an honest oversight something other than an error? Does there have to be some intent? A death occurs whether it is intentional or unintentional and that is always a serious matter. But, we are dealing with professionals.

So I do not understand, what you meant when you said you are not interested in really going after things like "honest oversight." I do not know what an honest oversight is, as compared to an error. But I do agree with your concerns and the size and nature of the problem.

Mr. COYNE. Well, we are really not going after anyone in either case. This is not legislation that is designed to determine fault, only the reason for the error. And if that information is reported and shared among health care professionals, I think that would go a long way toward not having them repeat it.

Mr. THOMAS. Well, my belief is, do you not think that the errors are, in fact, honest oversights?

Mr. COYNE. Yes. And the language could be changed to reflect that.

Mr. THOMAS. I am sure that Robin Cook can write a novel about it, which would make it clearly intentional on the part of some folk. But that would not be the ordinary experience.

In addition to that, the report requires a report of an error in the prescribing, dispensing, or administration of a drug. In each of those three provisions, prescribing is the responsibility of the medical doctor, I guess. And there you have questions of wrong dosage, overdosage, and misidentification.

And I do not see in the mechanics of what you report anything about the doctor or the writing of the prescription by the doctor under the subheadings on page 2, beginning with line 19. There is no identification of the person making the report, including the address and so on, line 23, the name brands of the drugs involved,

the generic names of the drugs, the manufacturers of the drugs, the labeler of the drug if different from the manufacturer, the dosage form of the drug, the strength of the drugs and the size of the container. Then you go on to 3, 4, 5, 6, 7, 8.

But I do not see anything here that refers to the prescription itself and whether or not there is an examination of errors in that universe.

Do we think about that? Are we going to deal with that?

Mr. COYNE. Well, in the instance of the doctor, he or she is likely to be prescribing that through the institution.

Mr. THOMAS. And is this only going to be hospital-based reporting?

Mr. COYNE. No. Wherever prescriptions are dispensed. And it would be that organization that would be what we are addressing in this legislation. That is, the pharmacy and the hospital, the pharmacy outside of the institution.

Mr. THOMAS. Maybe we can talk to people who have had this voluntary operation going for some time, but do we have any feeling for the errors being made, and do we have any feeling for where the errors occur?

If you divide it from the time that the prescription comes into the pharmaceutical structure, whether it be crossing over the Dutch door in the hospital or entering through the pharmacy, to what extent are the errors prepharmacy versus postpharmacy in terms of manipulation?

All of this seems to be focused fairly heavily on the drugs, the manufacturers, and that is the end of it. Do we have any information about the percentage of the problems that start simply because of the information on paper that began the process incorrectly?

I do not know if there is any information focused on "errors," but I would like to have a feel for who is fundamentally at fault here.

Does the pharmacist have the ability to take a prescription and look at it and realize that it is wrong and on their own say: "This is wrong"; or are they required to follow the prescription to the letter?

I am just interested in the exchange between the doctor and the pharmacist. And I think, frankly, more teamwork could possibly eliminate a lot of these errors. We are collecting all this data about the manufacturer, the laborer, and the lot number of the drugs which is going to produce a lot of information, but I do not know that it necessarily focuses directly on our desire to eliminate errors.

Mr. COYNE. Actually I think the language that says "prescribes, administers, and dispenses medications" would take into account those doctors who prescribe the medication.

Mr. THOMAS. OK. My theory is that the way to get rid of errors is to have multiple folk involved in the process, to the greater degree of cooperation and communication with each other. If perhaps the doctor is not as knowledgeable about the interaction of drugs or combinations of drugs or amount of dosage, then hire a professional pharmacist.

And I agree with you. There are going to be errors, honest oversights. We have to cut down on them. But I do not know that the collection of all of this data in the way in which you are asking for it is really going to provide a lot of information, and I do not know

where and how it is focused right now. I am going to have just to get a feel for it with the testimony.

Some of this stuff appears to be very useful. You need to know this. If you start with mandatory death and go forward, you are still missing a lot of the problem, because the problem in my opinion, is not the deaths, but the complicated, interrelated nature of drugs that we have today. There is an inability to solve the problem or creating additional problems for people in terms of quality of life.

And I would like to try to create a supportive, nurturing atmosphere, so that the professionals do more talking to each other, and there is a consultive relationship which produces a better dosage, a proper dosage, a correct determination.

And this is important, I think, but I do not know that it is focused in a way that gets me to a larger question.

The information that you reported was interesting. I am anxious to hear from the folks who apparently have been doing this on a voluntary basis, about where they think changes need to be made and their reaction to this bill in terms of going to another level.

But I, too, want to commend you on focusing on an area which is like the weather. Everybody talks about it, but nobody does anything about it. This is an attempt to do something about it.

Thank you.

Mr. COYNE. Thank you.

Chairman STARK. Just to make sure I understand the issue, I think that we will hear later today—and you are going to join us, Mr. Coyne?

Mr. COYNE. Yes.

Chairman STARK. The issue, as near as I can tell from the testimony to be presented, is the issue of the group of people who would like to keep this all voluntary. And so the discussion today will be voluntary, or should we require it.

It is my understanding that currently pharmaceutical manufacturers are mandated or required to report adverse reactions to the FDA and that—is that your understanding?

Mr. COYNE. That is correct.

Chairman STARK. And FDA now feels they get about only 1 percent through that route, that the manufacturers often do not hear about it. The doctor hears about it; the dispensing pharmacist hears about it.

The FDA has proposed similar adverse experience requirements for manufacturers of biological products. That is the FDA's recommendation currently. Is that your understanding?

Mr. COYNE. That is right.

Chairman STARK. Health care providers are required to report certain adverse events with specific vaccines under our Vaccine Injury Compensation. So that part is currently mandatory.

The FDA is currently preparing a rule to require or mandate, if you like that word better, adverse reaction reporting by manufacturers of nonprescription drug products that are approved.

The JCHO requires hospitals to make reports of serious adverse reactions to FDA as part of maintaining their accreditations. So that is a mandatory.

The AMA issued an opinion in 1993 that it is a physician's ethical responsibility and obligation to communicate an adverse reaction to the medical community, including the FDA, but they have not—but that is not—I do not know whether it was a State law, but that is an AMA—and that the FDA has issued a statement that health professionals should report, but that is hardly mandatory.

So I guess what—if I assess this properly, we kind of have a hodgepodge of some things are required and some things are not and that everybody agrees that we should know more about adverse reactions, including those that cause death; that there is some disagreement as to whether it should continue to be voluntary or be required.

Is that your assessment? Are there other issues that we will—that are contentious in this discussion, Mr. Coyne, in your opinion?

Mr. COYNE. Well, that is basically the issue. And so far as the legislation is concerned, it is in the incidence of where a death occurs as a result of a medication error.

To the extent that we would want to expand upon that, I think it would be based at least—

Chairman STARK. A big government advocate like myself might expand it; is that what you are worried about? I can tell. [Laughter.]

Mr. COYNE. That is what I was thinking, but I did not say it. [Laughter.]

Chairman STARK. OK. I just wanted you to frame the question and the problem that is before us.

Mr. THOMAS. Let's continue the line of questioning of what we are about or not about. The particular remedy that you have offered might be better served if we discussed the scope of the information. Some of it is more pertinent than others, and perhaps we could fund some items not initially thought of.

Perhaps some of the factors listed here might be questionable as to whether or not it was directly relevant to the question of committing errors. If it was a little more broader in scope it could be used for a number of other purposes. I would hope that the testimony would focus on the scope of the reporting requirements and whether or not they believe they are relevant to the question of focusing on errors.

I think that would be useful as well. Thank you, Mr. Chairman.

Mr. COYNE. I am sure that we will hear a lot of that testimony from the panels today that address those issues.

Chairman STARK. Well, thank you.

We will now have our first panel, which will consist of Dr. Joseph Valentino, who is the associate executive director of the United States of America Pharmacopeial Convention; Michael R. Cohen, who is president of the Institute for Safe Medication Practices; and David Work, who is the executive director of the North Carolina Board of Pharmacy.

We welcome this panel to the committee and ask that you summarize or expand on your prepared testimony, after which the committee can inquire.

Dr. Valentino, why do you not lead off.

STATEMENT OF JOSEPH G. VALENTINO, M.D., ASSOCIATE EXECUTIVE DIRECTOR, U.S. PHARMACOPEIAL CONVENTION, INC., ROCKVILLE, MD.

Dr. VALENTINO. Thank you very much. My name is Joseph G. Valentino, and I am the associate executive director of the U.S. Pharmacopeia.

I am accompanied today by Diane Cousins. Diane is the assistant executive director for our USP practitioner reporting programs, and I hope she will be able to help me answer some of your questions.

The USP is a private, not-for-profit organization. Our sole mission is to promote the public health by establishing and disseminating officially recognized standards for quality and authoritative information for the use of medicines, for medicines and related articles. The information is directed to professionals, patients, and consumers.

Because of our concern with the quality of drug products, in 1971 we cofounded the drug product problem reporting program. This is a national program in which health professionals are asked to report to us problems and defects with drug products.

Three years ago in 1991, we decided to focus more intensely on the problem of medication errors and what we could do to prevent them. Our focus is and remains primarily on the product. We do not set practice standards per se, but many of our standards do indirectly affect professional practice.

USP learned that the Institute for Safe Medication Practices, or ISMP, was seeking support of a national organization to bring its error reporting program to a national level, and we agreed to coordinate this national program for ISMP.

Since late 1991, this program has received more than 1,100 reports of actual and potential medication errors. We receive about 300 to 400 a year.

But during this time, we have also received over 1,000 medication errors reports from our other reporting programs, and these reports have identified errors in various health care delivery environments, including hospitals, nursing homes, physicians' offices, pharmacies, ambulances even, and home care.

By these reports we have seen that errors are multidisciplinary and multifactorial. They can be committed by experienced or inexperienced staff, by health professionals, support personnel, students, and even patients and their caregivers. They can occur anywhere along the continuum from prescribing, to transcribing, to dispensing, or administration.

The causes of the error may be attributed to human error, to the product name or the product design, to how the medication is handled, or to the delivery systems in which the products are used and how they operate and interact in the individuals.

For purposes of voluntary reporting, USP does not seek to limit the types of errors that may be reported, since all information received may have some future value. However, we do not actively solicit reports of adverse reactions.

Based on the statements of the myriad health professionals who report to the program, 71 percent of the reports reflect an event where an error actually occurred; 29 percent describe the possibility of an error to occur if there are certain predisposing factors.

Of the actual errors reported, 11 percent are reported to have resulted in a patient's death, and 9 percent were concerned and reported to be serious.

When we receive a report, we share it with the FDA and the manufacturer, and we seek to respect the desires of the reporter relative to keeping their identity confidential, and we attempt also to purge the identity of the institutions or any individuals named in the report.

We follow up with the reporters to the extent we can, either individually or we publish a newsletter called the Drug Product Quality Review.

But encouraging the reporting of errors is only one aspect. The information must be evaluated and necessary changes implemented to prevent recurrence of future errors.

USP shares the information in the medication error reports with the Committee of Revision, and we began to use the information provided almost immediately after we began to coordinate this program. I have examples in my testimony of some of the individual changes we have made.

But one change that we just recently made and which is in the new U.S. Pharmacopeia is that we have ceased to recognize the use of the apothecary system. This is a system, a centuries-old system of measurement, which pharmacists and physicians have utilized, in favor of the metric system, in order to avoid the misinterpretations which have led to overdoses.

We have also made changes in general labeling requirements for marketed drugs.

USP also publishes the USP DI. This is a drug reference recognized in the OBRA Acts of 1990 and 1993 as a source of standards for drug utilization and review for Medicaid and Medicare patients. And many State laws require pharmacies to have a copy of this text on hand.

We are considering including a section in each of the monographs to caution health professionals on drugs' proper use based on the reports we have received.

We are also seeking to expand the scope of the program. We are pursuing the involvement of State Boards of Pharmacy and trying to create a program for boards to submit reports of medication errors in their States. We hope that this will encourage boards to collect errors, and also we will be able to provide them with feedback information.

We have publicly stated that we will create 52 different systems, if necessary, to assist the boards, some of whom are resource-limited, to enable them to participate.

We have also used the MER data to create educational tools for health professions. In 1993, a curricular resource entitled "Understanding and Preventing Medication Errors" was distributed to all colleges of pharmacy in the United States, and I have a copy of it here for the subcommittee. And the plans are to distribute this to the other professions also.

We have attempted to reach the public directly, to teach patients how to protect themselves from medication errors through the development of a public service campaign called "Just Ask About

Your Medications," and I have a copy of one of the pamphlets for the subcommittee also.

We have been working to develop an increased awareness among health professions, associations, and regulatory bodies about medication errors.

We are contemplating the establishment of a medication errors review panel to review the reports and make recommendations regarding practice standards, dispensing systems, compendial standards, product design changes, et cetera. And we plan to establish a steering committee to be called the National Coordinating Committee for Medication Error Reporting and Prevention to act upon the review panel's recommendations.

Membership on this committee would consist of representatives of the compendia, State boards, and representatives of medicine, et cetera.

We have some recommendations. We believe the USP and the health professions should have the opportunity to improve the voluntary system for error reporting and to institute educational programs designed to reduce errors prior to imposing a mandatory error reporting system.

The voluntary system can be broader in scope and can capture potential error situations prior to their occurrence. This aspect cannot be successfully mandated. If a mandatory program is adopted, it should be careful to determine if it adversely affects voluntary reporting.

If a mandatory system is deemed necessary, we believe its scope should be limited to the reporting of deaths. The definition of what constitutes an error and the circumstances under which the report should be submitted should be clearly defined, so as to not adversely impact medical, pharmacy, or nursing practice.

We believe that such a system should preferably mandate reporting to a single agency involved with the practice or licensing in each State. If such a State mandatory system is initiated, we believe the State agency should share the appropriate information with the FDA and the USP, so that we can work to improve packaging and labeling.

In closing, let me assure you that the USP shares the goals that the public receives safe and effective medications without error, and that the government can continue to rely on the cooperation of the USP to accomplish this.

[The prepared statement follows:]

TESTIMONY OF JOSEPH G. VALENTINO, M.D.
UNITED STATES PHARMACOPEIAL CONVENTION, INC.

My name is Joseph G. Valentino. I am the Associate Executive Director of the United States Pharmacopeia. I am accompanied today by Diane Cousins, the Assistant Executive Director for USP Practitioner Reporting Programs.

BACKGROUND

The United States Pharmacopeial Convention, Inc. (USP), founded in 1820, is a private not-for-profit organization whose sole mission is to promote the public health by establishing and disseminating officially recognized standards of quality and authoritative information for the use of medicines and related articles for professionals, patients, and consumers. It is composed of approximately 400 members representing state associations and colleges of medicine and pharmacy, ten agencies of the federal government, and about 30 national professional, scientific and trade organizations, and members-at-large, including members from other countries that recognize USP standards. The USP's expertise as a standard-setting body has been recognized by Congress in the enactment of the Pure Food and Drug Act of 1906 and again by the Federal Food Drug and Cosmetic Act in 1938. The USP and NF are also referenced in most state pharmacy laws governing practice.

Because of our concern with the quality of drug products on the market, in 1971 the USP co-founded the Drug Product Problem Reporting Program - a national program to which health professionals, primarily pharmacists, were asked to voluntarily report problems and defects experienced with drug products on the market. Often the product problems or defects had to do with inadequate packaging or labeling - labeling which could lead to confusion on the part of health professionals or lead to errors, for example, similarity in color or design of the label, or look-alike, sound-alike drug names.

REPORTS RECEIVED

Three years ago, in 1991, USP decided to focus more intensely on the problem of medication errors and what we could do to prevent them. Our focus is and remains primarily on the product. USP does not set practice standards per se, but admittedly many of our standards do indirectly affect professional practice. The USP learned that the Institute for Safe Medication Practices (ISMP) was seeking support of a national organization to bring its program, The Medication Errors Reporting (MER) Program, to a national level. USP agreed to coordinate the national program for ISMP. The MER program is now one of five voluntary, spontaneous reporting programs for health care practitioners operated under the umbrella of the USP Practitioners' Reporting Network. Since late 1991, the USP-ISMP MER program has received more than 1,100 reports of actual and potential medication errors (approximately 300-400 reports per year). However, we have also received over 1,000 medication error reports during this time period from our other reporting programs. These reports have identified errors in various health care delivery environments including hospitals, nursing homes, physicians' offices, pharmacies, emergency response vehicles, and home care. By these reports, we have seen that errors are multi-disciplinary and multi-factorial. They can be committed by experienced and inexperienced staff, by health professionals, support personnel, students, and even patients and their care givers. They can occur anywhere along the continuum from prescribing to transcribing to dispensing and administration. The causes of errors may be attributed to human error, to product names or designs, or to the medication handling and delivery systems in which the products are used and individuals operate and interact. For purposes of voluntary reporting, USP does not seek to limit the types of errors that may be reported since all information received may have some future value. However, we do not actively solicit reports of adverse reactions.

Based upon the statements of the myriad health professionals who report to the program, 71% of reports reflect an event where an error actually occurred (called actual errors) and 29% of reports describe the possibility for an error to occur given certain predisposing factors (called potential errors). Of the actual errors reported, 11% (71) are reported to have resulted in a patient's death and 9% (58) were considered serious. As used here, the definition of "serious" is consistent with that used by the Food and Drug Administration in its reporting programs, i.e. life threatening, permanent impairment of body function, permanent damage to body structure, etc.

We recognize that an actual error may be reported as a potential error because of liability concerns, or a facility's risk management policies, so each report is treated with the utmost seriousness by USP and ISMP no matter how it is characterized by the reporter. As each MER report is received, it is shared with the product manufacturer and with the Food and Drug Administration. USP does not require that the name of the reporter, patient identity, or facility be given. However, if given, USP will respect the desires of the reporter to keep their identity confidential and will purge the identity of institutions or individuals named in the report in accordance with the instructions of the reporter. Reporters are also advised of any actions resulting from their report either individually or through the newsletter, *Drug Product Quality Review*.

CHANGES IN STANDARDS

Encouraging the reporting of errors is only one aspect. The information must be evaluated and necessary changes implemented to prevent the recurrence of future errors.

Medication error reports are shared with USP experts in its Drug Standards and Drug Information Divisions of the Committee of Revision. In its standards-setting role, USP began to use MER information almost immediately after it began coordinating the MER program.

The following examples describe some of the changes in standards or specifications that have been implemented or other steps taken by USP in response to these reports.

Deaths reported due to the accidental misadministration of concentrated Potassium Chloride Injection led to (1) changing the official USP name to Potassium Chloride for Injection Concentrate to give more prominence to the need to dilute the product prior to use; (2) labels must bear a boxed warning "Concentrate Must be Diluted Before Use; (3) the cap must be black in color (black restricted to this drug) and the cap must be imprinted in a contrasting color with the words, "Must be Diluted."

Deaths reported due to the confusion and resultant injection of the anticancer drug, Vincristine Sulfate for Injection, directly into the spine instead of into the vein, sparked changes in the requirements for packaging by pharmacies and manufacturers preparing ready-to-use doses. Each dose whether prepared by the manufacturer or the pharmacist must now be wrapped in a covering labeled "FOR INTRAVENOUS USE ONLY" and that covering may not be removed until the moment of injection.

In neither of these cases are we aware of misadministrations of the type described above since these requirements were invoked.

Reported medication errors have also brought about other changes in the compendia. For example, USP 23-NF 18 has ceased to recognize use of the apothecary system, a centuries old system of measurement, in favor of the metric system in order to avoid misinterpretations that have led to overdoses. USP has made changes in general label requirements for marketed drug products. For example, strengths less than one must be expressed as a decimal preceded by a zero (eg. 0.1 grams not .1 grams) to avoid ten-fold overdoses. The USP also requires that the strength of a product when expressed as a whole number be shown without a zero trailing the decimal to avoid ten-fold overdoses by the lack of recognition of the decimal point (eg. 1 mg not 1.0 mg).

DRUG USE INFORMATION

USP also publishes the *USP DI*®, a drug information reference recognized in the Omnibus Budget Reconciliation Acts of 1990 and 1993 as a source of standards for drug utilization review for Medicaid and Medicare patients. Many state pharmacy laws include the *USP-DI* as one of the reference texts a pharmacy must have on hand. MER reports of deaths have identified the need to establish dosing limitations for the sedative-hypnotic Chloral Hydrate for use in children, and for the anti-gout drug Colchicine. These dosing limitations have been incorporated into the *USP DI* information. Under consideration by our Advisory Panels is the creation of a section for each drug monograph to caution health professionals on the drug's proper use based on reports of errors received through the program.

Since FDA began receiving MER reports, it developed a more formal mechanism to evaluate these medication errors and the Subcommittee on Medication Errors was created from its Labeling and Nomenclature Committee. The Subcommittee now meets regularly to review reports and make recommendations to the FDA review divisions. USP and FDA have also created a joint advisory panel on the Simplification and Improvement of Injection Labeling to reduce medication errors. An initial report is included for the Subcommittee's information.

To expand the scope of the program, USP is pursuing the involvement of state boards of pharmacy by creating a program for the boards to submit reports of medication error incidents in their states. It is USP's hope that this database will assist each board in determining the relative extent of errors in that state, while contributing to the overall incident collection effort. At this time 18 states have contributed nearly 200 reports and an aggressive effort is being made this year to secure the support and participation of all boards of pharmacy. We have publicly stated that we will create 52 different systems, if necessary, to assist boards who are resource limited, to enable them to participate.

EDUCATION

In addition to using the MER reports for changes to enforceable standards and requirements in the *USP-NF*, and the drug information resource, *USP DI*, we have used the MER information to develop educational tools for the health professions. In 1993, a curricular resource entitled, Understanding and Preventing Medication Errors, was distributed at no charge to colleges of pharmacy throughout the U.S. The resource uses slides and case studies of actual medication errors in conjunction with role play exercises, a calculations quiz and a videotape to aid professors in the early training and sensitizing of our nation's future pharmacists. Programs are also being considered for medicine and nursing schools as well as continuing education and, for practice boards, a remedial instruction program for practitioners. A copy of the resource is being provided to the Subcommittee.

USP has also attempted to reach the public directly to teach patients how to protect themselves from medication errors through the development of the public service campaign called "Just Ask...About Your Medications," which is available at no charge. We are providing a copy of one of these pamphlets for the Subcommittee.

The USP has been working to develop an increased awareness among health professionals, associations, and licensing regulatory bodies about medication errors. We are contemplating the establishment of a medication errors review panel to review medication error reports and make recommendations regarding practice standards, dispensing systems, compendial standards, proper medication use, and product design changes. We plan to establish a steering committee to be called the National Coordinating Committee for Medication Error Reporting and Prevention to act upon the review panel's recommendations. Membership would consist of representatives of the compendia, ISMP, state boards of pharmacy, medicine, and nursing, the FDA, professional associations, the Joint Commission on the Accreditation of Healthcare Organizations, and consumers.

Aside from USP activities, in response to the Medicaid and Medicare provisions of the 1990 and 1993 Omnibus Budget Reconciliation Acts, over 40 states have recently adopted mandatory counseling provisions for pharmacists. We believe these counseling requirements have a potential to reduce medication errors in the outpatient system.

RECOMMENDATIONS

In view of the increased efforts of the USP, the health professions, and recent state legislative enactments, we would make the following recommendations:

1. We believe the USP and the health professions should have the opportunity to improve the voluntary system for error reporting and to institute educational programs designed to reduce errors, prior to imposing a mandatory error reporting system. The voluntary system can be broader in scope and "capture" potential error situations prior to their occurrence. This aspect cannot be successfully mandated. If a mandatory program is adopted, it should be carefully monitored to determine if it adversely affects voluntary reporting.
2. If a mandatory reporting system is deemed necessary, we believe its scope should be limited to reporting of deaths. The definition of what constitutes an error and the circumstances under which reports should be submitted should be clearly defined so as not to adversely impact medical, pharmacy or nursing practice. We believe such a system should preferably mandate reporting to a single agency involved with practice or licensing in each state.
3. If such a state mandatory system is initiated, we believe the state agencies should share the appropriate information with the Food and Drug Administration and the United States Pharmacopeia so that improved packaging and labeling for drugs can be required, improved uniform dispensing systems developed, and educational information made available.

In closing let me assure you that the USP shares the goals that the public receive safe and effective medications without error and that the government can continue to rely on the cooperation of the USP to accomplish this.

Mr. COYNE [presiding]. Thank you, Doctor.
Mr. Cohen.

**STATEMENT OF MICHAEL R. COHEN, M.S., FASHP, PRESIDENT,
INSTITUTE FOR SAFE MEDICATION PRACTICES**

Mr. COHEN. Good morning, Mr. Coyne and other members of the Subcommittee on Health.

I would also like to thank you for the opportunity of making a presentation here this morning. I am Michael Cohen, and I am a pharmacist, and I am here representing the Institute for Safe Medication Practices, or ISMP.

ISMP is an independent nonprofit organization that works in concert with the medication reporting program coordinated by the U.S. Pharmacopeia, and our role in the program is to provide an analysis of those confidential reports that come in voluntarily, submitted by health care practitioners to the USP.

We utilize the information gained from this program to prevent medication errors by educating the health care community about their circumstances and causes, and errors or near errors reported through the program include administering the wrong drug or giving the wrong strength or dose of a medication, confusion over look-alike or sound-alike drugs, incorrect route of administration, miscalculations, misuses of medical equipment, errors in prescribing and transcribing. These are preventable situations.

The program emphasizes improvements in professional practice, as well as in the names assigned to pharmaceutical products, the warning systems used, the drug packaging labeling, and drug delivery system design.

Recommendations often stem from our reporters' suggestions, as well as volunteer practitioner consultants working with ISMP, and we have a panel of nurses and pharmacists who react to medication errors that are reported that we bring to them.

By corresponding about specific issues with FDA, pharmaceutical companies and the health care industry, we provide an important oversight to assure that problems are being addressed. We act as an independent organization in this way.

We communicate with the health care community through regular medication errors features in nine different publications each month. The columns are different. We also communicate through electronic bulletin boards with pharmacists, so that we can alert them immediately if there is a very serious situation that has come to light.

We reach the membership of the American Society of Hospital Pharmacists, the American Pharmaceutical Association, the American Nursing Association, and we have plans in the future to also reach the American Medical Association members.

Actually we are reaching now about 1½ million health professionals each month with these columns, and actually we have been doing medication error reporting columns since 1975 until we became a nonprofit organization. We did this on our own through a journal called Hospital Pharmacy.

We assume we will be reaching an additional 100,000 pharmacists, practically all the pharmacists in the country, through a new APHA newsletter, which will be produced shortly.

Case studies have been published on more than 1,000 reports since we began, alerting health care professionals about practice-related issues as well as the labeling and packaging and nomenclature that may encourage error by their design, things that may have passed the FDA test but not the practitioner test.

And I think there has been a natural evolution that is important for you to know about, and that we may have started out as individuals, but working with USP has had a major impact within the past few years on improvements by the health care community in general. I think the program has gotten much more respect and much more publicity than it had when we started out.

As necessary, ISMP also conducts national meetings where we draw together practitioners, the industry, FDA, to talk about serious problems that are going unresolved and figure ways that we can prevent them; for example, a potassium chloride continuing problem with medication error related deaths many years ago was resolved at a national meeting and then followed through by the USP where they put black caps, enclosures, and warnings on the containers, and since that has occurred, the problem of mixups between potassium and similar-appearing vials has been totally diminished in the United States, at least.

We have worked with the lay press to cover particularly serious medication error issues. For example, we have conducted a national meeting and also appeared on network television to discuss unresolved situations involving lidocaine syringes, later withdrawn from the market, and more recently on American Journal and The Crusaders, we discussed deaths resulting from poorly designed intravenous infusion equipment, which has not been totally resolved, but which we believe should be and which we will continue to monitor and work with FDA to get the changes made.

The Food and Drug Administration has several projects underway that are important for you to know about that perhaps you can ask during questioning, as does the Pharmaceutical and Research and Manufacturing Association.

Obviously much more needs to be done, and not all problems are being addressed. We would like to see the program grow.

Many people believe that a mandatory program should be developed that would require institutions to report to a governmental agency any medication errors which have resulted in death or injuries, and these people have good intentions, but such a proposal, we feel, should be studied very carefully, because it could actually have a negative overall effect on reducing medication errors and injuries.

Mandatory reporting would increase reports, but this, in itself, is not solving a problem. It is what is done with the information. And we are concerned that confidentiality restrictions imposed on governmental agencies would impede the free flow of information about reported errors. They cannot do with the information what we are able to do, picturing the errant products, et cetera, and issuing warnings on our own.

What we are saying is, we believe that an independent voluntary system can capture information better than a governmental system and do more with the information. And I have summarized in my appendices a number of major problems that have been fixed, as

well as the benefits of our current voluntary program versus the required reporting program.

Finally, we believe that public health is best defended when health care practitioners, institutions, industry, and the regulatory agencies and patients join together and not work alone, and we believe that the current voluntary reporting effort offers the best chance for such cooperation.

We appreciate the opportunity to present our views, and we look forward to serving as a resource to you as you seek ways to improve patient safety.

Thank you.

[The prepared statement and attachments follow:]

TESTIMONY OF MICHAEL R. COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES

[This statement on behalf of the Institute for Safe Medication Practices (ISMP), is presented by Michael R. Cohen, MS, FASHP. Mr. Cohen is president of ISMP, adjunct associate professor of pharmacy at Temple University, and Assistant Editor of the journal Hospital Pharmacy. Mr. Cohen and colleague Neil M. Davis, Pharm D, FASHP, professor emeritus at Temple University, co-founded the national Medication Error Reporting Program in 1975. Since 1991, the program has been coordinated by the United States Pharmacopeia].

Good morning Mr. Chairman and members of the Subcommittee on Health. My name is Michael R. Cohen. I am a pharmacist and I am here representing the Institute for Safe Medication Practices (ISMP).

ISMP is an independent nonprofit organization that works in concert with the Medication Error Reporting Program coordinated by the United States Pharmacopeia. Our role in the program is to provide an analysis of confidential reports voluntarily submitted by health care practitioners to USP. We utilize information gained from the program to prevent medication errors by educating the health care community about their circumstances and causes. Errors or near errors reported through the program are:

- administering the wrong drug, strength, or dose
- confusion over look-alike/sound-alike drugs
- incorrect route of administration
- miscalculations
- misuse of medical equipment
- errors in prescribing and transcribing

The program emphasizes improvements in professional practice, as well as in the names assigned to pharmaceutical products, the warning systems used, drug packaging and labeling, and drug delivery system design. Recommendations often stem from the reporters suggestions as well as volunteer practitioner consultants working with ISMP.

By corresponding about specific issues with FDA, pharmaceutical companies and the health care industry, we provide important oversight to assure that problems are being addressed appropriately. An important feature of our program is that we communicate with the health care community through regular medication error features in a number of professional journals and electronic bulletin boards. We reach over 1.5 million health care practitioners monthly (please see Appendix I). Case studies have been published on more than 1000 reports, alerting health care professionals about practice related issues as well as labeling and packaging or nomenclature that may encourage error by their design.

As necessary, ISMP conducts national meetings or utilizes press releases or publications to alert professionals of potential problems that we believe are not being addressed in appropriate fashion. We have worked with the lay press to cover particularly serious medication error issues that have gone unresolved. For example, we have conducted a national meeting and appeared on network television to discuss an unresolved situation involving concentrated lidocaine syringes, later withdrawn from the market. More recently on *American Journal* and the *Crusaders*, we discussed deaths resulting from some poorly designed intravenous infusion equipment. Industry responded by designing fail-safe protection methods which have been adapted in many hospitals and we will continue to work on this matter until all devices are protected. FDA published a public health advisory on this matter earlier this year.

We have observed a great deal of attention and progress in addressing medication error issues in recent years. For example, the American Society of Hospital Pharmacists (ASHP) has published guidelines for preventing medication errors in hospitals. The American Medical Association (AMA) House of Delegates endorsed a policy earlier this year and final work on a guideline statement for physicians is now underway. Next month, ASHP, AMA and the American Nurses Association (ANA) will jointly conduct an invitational conference to make recommendations about activities that need to be undertaken to address the issue of drug misadventures.

The Food and Drug Administration has several major efforts underway to properly analyze the potential for user error with labeling, packaging and brand names. Last year, the agency established two committees which address medication error issues: *The Nomenclature and Labeling Committee* screens proposed trademarks for potential problems, and a *Subcommittee on Medication Errors* was established to review medication error reports submitted by ISMP or received through the agency's MedWatch program. FDA maintains open communication channels with USP and ISMP regarding medication error issues.

Members of the Pharmaceutical Research and Manufacturers of America (PhRMA) established a Committee to Reduce Medication Errors on which ISMP served. The purpose of this group was to establish guidelines to simplify and improve injection labeling in the hope of reducing medication errors due to package label confusion. The results of this Committee's work was considered by a joint USP-FDA Panel and their recommendations were just published in the July/August *Pharmaceutical Forum*. Most important, many long-standing problems have been addressed or are in process. Appendix II lists the major drug product-related issues reported to the USP-ISMP program along with their resolution or current status.

Much more needs to be done. Certainly not all medication error problems have been addressed, and there will always be new problems. We recognize that our program needs to grow in order to expand our educational and informational activities and reach the remainder of the health care community beyond nurses and pharmacists. We need to be able to respond to an ever increasing number of requests from institutions and practitioners for information about error prevention methods. We need to develop methods for expanding our alert system in response to newly reported, dangerous errors. We need to be able to enhance our efforts in communicating with industry.

FDA's efforts to reduce drug product-related medication errors must continue to receive appropriate support. No pharmaceutical company should be permitted to duck ongoing medication error issues involving their products, as some have. Many people believe that a mandatory system should be developed that would require institutions to report to a governmental agency, any medication errors which have resulted in death or serious injury. These individuals have good intentions, but such a proposal would need to be studied very carefully because it could actually have a negative overall effect on reducing medication errors and patient injuries.

Mandatory reporting would increase reports, but this in itself is not solving a problem. It's what is done with the information that is important. We are concerned that confidentiality restrictions would impede the free flow of information about reported medication errors from the government back out to practitioners and institutions. They simply can't do what we do,

picturing offending products in journal articles, sending out press releases, reacting to practice related (non-product related) medication errors, etc. Reports would be available to us as independents only through a Freedom of Information Act request, and we would not be able to contact reporters to learn the full extent and circumstances surrounding the problem; information often missing from reports.

What we are saying is that we believe that an independent voluntary system can capture information better than a governmental system and do more with the information. In Appendix III, I have summarized the benefits of the current voluntary practitioner reporting program compared to a mandatory program and also listed ISMP's concerns about mandatory reporting of errors to the government. These are important points, and I welcome the opportunity of providing further explanation or answering any questions that you might have. The government should not be pressured into something new when a need is already being met voluntarily by an independent organization with an effective system already in place.

It is also important to note that right now, a single voluntary report to us is enough to stimulate action to prevent further mishaps. We do not wait to accumulate large numbers of reports. In fact, a mandatory system will not reveal near misses and suspected problems which could lead to improvements before any deaths occur. This is vital information that would be missed.

Little, if anything, would be added to our level of knowledge about errors or the ability of FDA or anyone else to take action to prevent them. We certainly encourage increased reporting, but ISMP believes this could easily be accomplished by inclusion of a provider accreditation standard which would require sites to report medication errors in the same way they are required to report adverse drug reactions to the FDA. Also, the number of reports will naturally increase with program expansion and promotion to reach new audiences.

ISMP believes that the public health is best defended only when health care practitioners, institutions, industry, regulatory agencies and patients join together to address medication safety issues. ISMP believes that the current voluntary effort offers the best chance for such cooperation. We appreciate the opportunity to present our views and look forward to serving as a resource to Congress as it seeks ways to improve patient safety.

Appendix I

Educational Outreach

ISMP pharmacists communicate directly with over 1.5 million health professionals monthly through ongoing medication error prevention features.

Professional journals and newsletters:

- *Hospital Pharmacy* (J. B. Lippincott Company)
- *American Pharmacy* (American Pharmaceutical Association)
- *American Journal of Nursing* (American Nursing Association)
- *Nursing Magazine* (Nursing '95, etc.) (Springhouse Corporation)
- *IV Newslite* (Intravenous Nurse Society)
- *ASHP Newsletter* (American Society of Hospital Pharmacists)
- *Home Care Highlights* Newsletter (ASHP Section of Home Care Practitioners)

Electronic bulletin board services:

- *FLX*® (Formulary Information Exchange)
- *PharmNet*® (ASHP)
- *PediNet*® (Pediatric Pharmacists Administrative Group)

Global Efforts to Reduce Medication Errors

In cooperation with the American Society of Hospital Pharmacists (ASHP) and the Federation Internationale Pharmaceutique (FIP, the International Pharmaceutical Society), ISMP will co-host the First Global Conference on Medication Error Reporting Programs in Miami Beach, FL, December 6, 1994.

Appendix II

Examples of USP-ISMP Error Reduction Activities

- A federal requirement that potassium chloride concentrate injections have black caps, closures and warning statements to differentiate them from all other pharmaceuticals in order to prevent dangerous mix-ups with other parenteral containers. No case of look-alike vial mix-up has been reported since this change took effect.
- Special hazard warnings and labeling practices for vincristine injection in order to help health professionals overcome repeated problems with accidental intrathecal injection. Since this requirement took effect several years ago, not a single case of accidental injection has been reported to FDA or USP. FDA is recommending to the World Health Organization that a similar requirement be adopted globally.
- A national meeting to discuss elimination of lidocaine 1 and 2 g concentrate prefilled syringes due to numerous reports of error-related deaths. These products were removed from the US market in 1993.
- A campaign for inclusion of a "purpose/indication" statement on prescription blanks and in drug advertisements. Recently, the State of Texas adopted such a requirement.
- ISMP has successfully campaigned for revision of pharmaceutical advertisements which depict the use of potentially dangerous prescription practices, including dangerous medical abbreviations, ambiguous prescription writing, and omission of important prescription information such as strength, directions, etc.
- Clarification of dose statements in the USP DI® (an official OBRA '90 text) for chloral hydrate syrup and colchicine injection, adding new limits per course of therapy in order to allay confusion.
- A USP requirement that doses expressed as a decimal number smaller than one shall be shown with a zero preceding the decimal (example, 0.1 mg not .1 mg). A USP requirement that the quantity of active ingredient when expressed in whole numbers shall be shown without a decimal point that is followed by a terminal zero (1 mg not 1.0 mg).
- A decision by USP to no longer recognize the apothecary system of measurement.
- Volunteer and mandatory trademark changes for several products involved in look-alike/sound-alike errors. Changes in nonproprietary names have been made by USAN for similar reasons.

The following ideas for USP action have resulted from voluntary practitioner reporting to the USP-ISMP Medication Error Reporting Program:

- development of standardized abbreviations in prescription writing
- cisplatin-carboplatin nomenclature
- clarification of dose limitations for vincristine and cisplatin
- requirements for packaging of medications in foil overwraps
- requirements for labeling of premixed IV containers on both sides of IV bags

Other Activities and Projects

- Removal of the apothecary scale from US manufactured plastic disposable syringes. Contributing to the elimination of the apothecary system of measurement from the USP.
- Working with the Pharmaceutical Research and Manufacturers of America's (PhRMA)

Committee to Reduce Medication Errors by improving labeling of small volume parenterals regarding concentration and volume.

- Lobbying manufacturers to improve labeling of large volume parenterals to include an additional label on the back side of product containers. A major parenteral manufacturer and a small generic parenteral manufacturer have already implemented such labeling.
- Encouraging safety recommendations and warnings regarding automated IV compounders, syringe pumps, patient controlled analgesia (PCA) pumps, infusion pumps and free flow.

Appendix III -

Concerns about mandatory reporting of medication errors to U.S. Government

- Mandatory reporting of medication errors is likely to increase the number of reports received, but would not be expected to provide new information above what is already available through voluntary practitioner reporting. Epidemiological information would be suspect because there can be no guarantee that all covered incidents will be reported. Some medication errors are not discovered. Others may not be reported due to ignorance about requirements.
- Mandatory reporting is being proposed for medication errors which have actually resulted in death or injury. Reporting of near misses would not be required. Yet, the near miss reports could provide important information which might preclude any deaths at all. The voluntary reporting actively solicits such reports.
- Mandatory reporting may decrease voluntary reporting, as professionals might be hampered due to confidentiality concerns, assumption that the error has already been reported, or confusion over what needs to be reported to the voluntary program versus any mandatory program.
- A mandatory reporting program could be costly for hospitals to operate and will require new government activities, as has the Safe Medical Devices Act of 1990.
- Due to confidentiality requirements imposed by law upon FDA, it will restrict the current free flow of information to hospitals, professionals, and the public, which is now provided through voluntary reporting to the USP-ISMP Medication Error Reporting Program.
- The great majority of serious medication errors have involved poor labeling, packaging, and naming of pharmaceuticals, or poor regulatory requirements (official labeling, advertising, marketing, etc.). Therefore, an important system of checks and balances is provided by an independent, practitioner-oriented organization. In all cases, the current voluntary program receives the report and forwards a copy to FDA for their own use. Confidentiality laws prevent FDA from forwarding reports received by them to ISMP. Thus reports are not readily available for educational purposes and tracking to assure improvements are made. Also, in order to receive a MedWatch report, FDA employees entail a time consuming procedure in copying reports and reviewing them to assure all identification has been removed. The copied reports are difficult to read and much information will be missed.

Reasons for voluntary reporting through USP-ISMP:

- USP is an FDA MedWatch partner, so all USP-ISMP MERP reports go to FDA automatically - at no charge to the government. By reporting to the USP-ISMP MERP, two actions are taken with one report. Any deaths or serious injuries are phoned to FDA upon receipt.
- All Medication Error Reports are reviewed by practitioners. When a report is sent to ISMP, it is reviewed by ISMP staff. As necessary, a panel of practicing pharmacist and nurse volunteers is consulted. ISMP works independently of the FDA, USP and the manufacturer. It reviews information from the report, conducts an investigation when necessary, and makes recommendations to these groups along with a copy of the report. There are situations when the FDA and the manufacturer need to hear from ISMP about error situations, to make sure that the significance of a particular situation to practitioners is understood and to provide guidance and suggest overall system changes.

- Where necessary, explicit product names are depicted in published case studies. We reveal poorly conceived drug names, and picture poor labeling and packaging in our publications. The publication of such information serves an important function because it may be a stimulus for problems being corrected by manufacturers. Many changes can be traced to such open critique by practitioners.
- For educational reasons, we publish many of the reports sent to us. ISMP publishes editorial comments and photographs of actual problematic drug packages, labels, and names. As previously noted, confidentiality requirements prevent the FDA from publicizing the material in this manner and thus, it is difficult for the agency to provide the same level of education that we, as private citizens, can provide.
- Besides press releases, monthly articles on medication error topics reach over 1.5 million health care practitioners each month in journals, newsletters and electronic outlets, including: *American Journal of Nursing*, *Nursing 94*, *Hospital Pharmacy*, the *ASHP Newsletter* (American Society of Hospital Pharmacists), *Home Care Highlights Newsletter* (ASHP Section of Home Care Practitioners), *American Pharmacy* (American Pharmaceutical Association), and three national computer bulletin board services *FIX*® (Formulary Information Exchange), ASHP's *PharmNet*®, and *PediNet*® (Pediatric Pharmacists Administrative Group). This year, we will also begin publishing in the newsletter of the American Pharmaceutical Association, reaching nearly every pharmacist in the United States. All communications are published anonymously. In nearly 20 years, we have never revealed the source of a report to anyone. The USP and ISMP organizations have produced and made available at no charge, a slide/videotape curricular resource for colleges of pharmacy. A similar program will soon be made available for use in nursing and medical education.
- Manufacturers are automatically informed. Manufacturers receive, at no charge, any medication error report mentioning their product. Also, a follow-up phone call or letter listing our recommendations is sent where warranted. Where necessary, we act as an intermediary between FDA, USP, manufacturers and reporters who wish their identity to remain confidential. In response to a specific medication error, ISMP offers, at no charge to the manufacturer, an assessment of labeling and packaging and a written report submitted.
- Practice related medication errors are of concern to us. Practice-related and system-related medication error reports are processed by ISMP. Guidelines and recommendations are often published by ISMP or provided directly to a facility or practice site. While the government is interested in knowing about problems, taking action is not normally considered to be within their realm. Since we represent practitioner interests, causes of error such as miscalculation, incorrect patient identification, pumps that are set incorrectly, medication given to wrong patient, etc. are reviewed by us and commented upon in our journal publications with recommendations to practitioners. The program has long advocated a high level of pharmacy service to lessen error potential.
- USP-ISMP MERP reporting has a good track record. We are proud of the MERP's excellent track record which has contributed to the positive changes and improvements made by all concerned groups. Relationships have been formed with professional organizations and approval agencies and liaisons are maintained with error prevention experts outside of ISMP. ISMP supports medication error research projects by making information and reports available. ISMP fields hundreds requests for assistance with error prevention information from nurses, pharmacists, risk managers, hospitals, etc. Information from our files is sent at no charge.
- Information reaches practitioners and industry much more quickly when error reports are sent to the USP-ISMP Medication Error Reporting Program. Materials and information

are made available much faster to practitioners through ISMP rather than having to go through the FDA's Freedom of Information (FOI) process. FDA personnel must code each MedWatch report for medication error (the MedWatch form does not have a section for medication errors), retrieve these, blot out any identity, and copy the reports for us. Reports sent to the MERP directly by reporters allow us access to information without an expensive and time consuming FOI request.

- We need to be able to communicate with reporters. Because of government confidentiality requirements, we cannot learn the identity of reporters to MedWatch and thus cannot communicate directly with them to learn of important information surrounding the report. Such information is often inadvertently omitted by reporters. Thus our understanding of the circumstances surrounding an error may be impaired.

About the Institute for Safe Medication Practices

The Institute for Safe Medication Practices (ISMP) is a non-profit organization dedicated to maximizing patient safety through collection, analysis, and publication of accounts of medication errors. ISMP has evolved from medication error prevention work carried out from 1975 through 1990 by pharmacists Michael Cohen and Neil Davis, and until 1993, through a company founded by them. In order to expand its commitment to public health and education, since January, 1994, these activities have been carried out through the non-profit corporation. Application for tax exempt status is pending with IRS.

Mr. COYNE. Thank you, Mr. Cohen, for your testimony.
Dr. Work.

**STATEMENT OF DAVID R. WORK, J.D., EXECUTIVE DIRECTOR,
NORTH CAROLINA BOARD OF PHARMACY**

Mr. WORK. Thank you, Mr. Chairman, for allowing me to testify on this most important issue before you, the reporting of deaths due to the legitimate pharmaceuticals used by health professionals in the course of their practice.

I am David Work, the executive director of the North Carolina Board of Pharmacy, which is the licensing board for pharmacists and pharmacies in our State. I am also an adjunct professor of pharmacy law at the University of North Carolina School of Pharmacy in Chapel Hill. Last year, I served as president of the National Association of Boards of Pharmacy, and I am currently the chairman of its executive committee.

I am here as executive director of the North Carolina Board, and I need to thank the members of the board for whom I work for giving me permission to appear at this hearing.

The board is holding its regular monthly meeting today for disciplinary actions and to conduct other business, and I have missed only two other board meetings during the last 18 years due to illness and another time when I was not in the country.

In order to place my testimony in perspective, I believe it would be helpful to give a brief history of our board's experience with the death reporting program.

In February 1988, we learned through press reports of two deaths at a Charlotte hospital. We investigated the matter and found that two patients had died due to an error which began in the pharmacy, causing the wrong solution to be pumped through the hearts of two patients. One of these patients was 33 years old. If it had not been for the diligent reporting by a Charlotte Observer newspaper reporter, Karen Garloch, we would not have known of this tragic event.

After investigation and much legal maneuvering, our board held disciplinary actions for the pharmacist involved, the director of the pharmacy, and the permit to operate the pharmacy at the hospital. All received sanctions from the board.

During this public hearing, the public member of our board, Mr. Biggers, noted that this event would have been unknown but for the newspaper reports and inquired as to any legal duty to report this matter. We could find none. All of this and more is reported in "The Great White Lie" written by Walt Bogdanich and is referenced in my testimony.

This was an exceptionally difficult investigation. It was conducted by our assistant director of inspection, Steve Hudson, and lasted over 6 months. For his work on the case, Mr. Hudson received the Distinguished Service Award from our national organization.

About 3 years later, we were made aware of a death at a teaching medical center in Durham from a report to our office by a pharmacy employee. Through a series of actions, at least five physicians and pharmacists participated in a tragic event which caused the death of a 5-year-old boy. The Board of Pharmacy sanctioned two

pharmacists for their activity, and anyone would be moved to tears by the comments in the medical record by the boy's mother, which was introduced as evidence during the disciplinary hearing.

At this point the board staff decided to pursue the matter first raised by our public member with a rule requiring the reporting of deaths due to drugs dispensed through pharmacies. At the public hearing on the rule, both the North Carolina Society of Hospital Pharmacists and the North Carolina Pharmaceutical Association supported the proposed rule. They requested a periodic review, and that is contained in part of my written testimony, as is the rule itself. The effective date of the rule is March 1, 1992.

During the first year of this rule, 10 deaths were reported due to drugs. We received some surprises from this information. First of all, we expected that most, if not all, deaths would be in hospitals, but that was not the case. During the first year, half the reports came from retail pharmacies where we are fairly sure that events are greatly underreported. The most retail pharmacists may know is that the patient did not come back for refills.

In addition, we believe that at least three of these deaths were preventable with patient counseling by the pharmacist, which is now required, but was not required at that time.

In my written testimony, there is a summary chart of each of these deaths during the first year.

We were surprised to find that 3 of these 10 deaths were due to procainamide in one form or another, and that all but one of the deaths involved females. These unexpected results did not continue in the second year.

At this point, our data is that there were 10 deaths reported the first year, 13 the second year, and we have 15 reports so far this calendar year. From these numbers, recognizing that there is some underreporting—and we have no data on OTC drugs—we believe that about 10,000 deaths occur nationwide from pharmaceuticals each year.

One more point deserves emphasis. Problems not only occur with prescription drugs, but also with over-the-counter drugs. Just last year, for example, there were three deaths in 1 week in Charlotte, N.C. due to Tylenol. These occurred after the individuals had ingested a substantial amount of beer and then consumed Tylenol.

In case you are not aware of this situation, Tylenol was once a prescription drug that was switched to OTC status in the early 1960s. There have been several prescription drugs recently moved to OTC status, such as ibuprofen and most recently naprosyn, and many more such moves are planned in the future. There is no doubt that our society faces more problems in this area when such drugs are combined with prescription drugs and alcohol.

A key element for the success of any death-reporting program is the trust which physicians, pharmacists, hospital administrators, and others have that they will not be fed into a government meat grinder. There is a natural resistance to reporting such events, and it does not help for such reports to go to a marble building in Washington, such as the one in which we are testifying today.

We have not treated these reports as an admission of culpability, but only as an event. Each has been investigated. And of nearly 40 reports, only one was brought to the board on a hearing for neg-

ligence. This has helped reassure the medical community that a death report is not automatic trouble for them. State agencies are much closer to health professionals than the Federal Government and generally more trusted than Washington authorities. Most State agencies also have subpoena power and an investigative staff to gather facts for thorough and complete reports.

For this reason, I believe the best way to go is a mandatory system. It is my recommendation that there be mandatory reporting of deaths due to OTC or prescription drugs to State agencies such as Boards of Pharmacy or Health Departments with appropriate provisions for confidentiality and compilation at the national level. This information could then be used to guide and improve practice to better protect the public health and safety.

And thanks for allowing me to testify, and I am open to your questions.

[The prepared statement follows:]

**TESTIMONY OF DAVID R. WORK
NORTH CAROLINA BOARD OF PHARMACY**

THANK YOU MR. CHAIRMAN FOR ALLOWING ME TO TESTIFY ON THIS MOST IMPORTANT ISSUE BEFORE YOU - THE REPORTING OF DEATHS DUE TO LEGITIMATE PHARMACEUTICALS USED BY HEALTH PROFESSIONALS IN THE COURSE OF THEIR PRACTICE. I AM DAVID WORK, THE EXECUTIVE DIRECTOR OF THE NORTH CAROLINA BOARD OF PHARMACY WHICH IS THE LICENSING BOARD FOR PHARMACISTS AND PHARMACIES IN OUR STATE. I AM ALSO AN ADJUNCT PROFESSOR OF PHARMACY LAW AT THE SCHOOL OF PHARMACY, THE UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL. LAST YEAR I SERVED AS PRESIDENT OF THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY AND AM CURRENTLY THE CHAIRMAN OF ITS EXECUTIVE COMMITTEE. I AM HERE AS THE EXECUTIVE DIRECTOR OF THE NORTH CAROLINA BOARD AND NEED TO THANK THE MEMBERS OF THE BOARD, FOR WHOM I WORK, FOR GIVING ME PERMISSION TO APPEAR AT THIS HEARING. THE BOARD IS HOLDING ITS REGULAR MONTHLY MEETING TODAY FOR DISCIPLINARY ACTIONS AND TO CONDUCT OTHER BUSINESS AND I HAVE MISSED ONLY TWO BOARD MEETINGS DURING THE LAST 18 YEARS, ONE DUE TO ILLNESS AND ONE LAST YEAR WHEN I WAS TRAVELING OUTSIDE OF NORTH AMERICA FOR THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY. THE MEMBERS ARE ALBERT LOCKAMY, JR., PRESIDENT; WILLIAM H. RANDALL, JR., VICE PRESIDENT; WILLIAM T. BIGGERS, PUBLIC MEMBER; JACK G. WATTS; HAROLD VANN DAY AND WILLIAM WHITAKER MOOSE. IN ORDER TO PLACE MY TESTIMONY IN PERSPECTIVE, I BELIEVE IT WOULD BE HELPFUL TO GIVE A BRIEF HISTORY OF OUR BOARD'S EXPERIENCE WITH A DEATH REPORTING PROGRAM.

IN FEBRUARY OF 1988 WE LEARNED THROUGH PRESS REPORTS OF TWO DEATHS AT A CHARLOTTE HOSPITAL. WE INVESTIGATED THE MATTER AND FOUND THAT TWO PATIENTS HAD DIED DUE TO AN ERROR WHICH BEGAN IN THE PHARMACY CAUSING THE WRONG SOLUTION TO BE PUMPED THROUGH THE HEARTS OF TWO PATIENTS. ONE OF THESE PATIENTS WAS 33 YEARS OLD. IF IT HAD NOT BEEN THROUGH DILIGENT REPORTING BY A CHARLOTTE OBSERVER NEWSPAPER REPORTER, KAREN GARLOCH, WE WOULD NOT HAVE KNOWN OF THIS TRAGIC EVENT. AFTER INVESTIGATION AND MUCH LEGAL MANEUVERING OUR BOARD HELD DISCIPLINARY HEARINGS FOR THE PHARMACIST INVOLVED, THE DIRECTOR OF PHARMACY AND THE PERMIT TO OPERATE THE PHARMACY AT THE HOSPITAL. ALL RECEIVED SANCTIONS FROM THE BOARD. DURING THIS HEARING THE PUBLIC MEMBER OF OUR BOARD, MR. WILLIAM T. BIGGERS, NOTED THAT THIS EVENT WOULD HAVE BEEN UNKNOWN BUT FOR THE NEWSPAPER REPORTS AND INQUIRED AS TO ANY LEGAL DUTY TO REPORT THIS MATTER. WE COULD FIND NONE. ALL OF THIS AND MORE IS REPORTED IN THE GREAT WHITE LIE, SIMON & SCHUSTER (1991), WALT BOGDANICH, CHAPTER 4.

THIS WAS AN EXCEPTIONALLY DIFFICULT INVESTIGATION. IT WAS CONDUCTED BY OUR ASSISTANT DIRECTOR OF INSPECTION, MR. STEVE HUDSON, AND LASTED OVER 6 MONTHS. FOR HIS WORK ON THIS CASE MR. HUDSON RECEIVED THE DISTINGUISHED SERVICE AWARD FROM THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY. HE IS ONE OF ONLY TWO PHARMACY BOARD INVESTIGATORS TO RECEIVE THIS HONOR.

ABOUT THREE YEARS LATER WE WERE MADE AWARE OF A DEATH AT A TEACHING MEDICAL CENTER IN DURHAM FROM A REPORT TO OUR OFFICE BY A PHARMACY EMPLOYEE. THROUGH A SERIES OF ACTIONS AT LEAST FIVE PHYSICIANS AND PHARMACISTS PARTICIPATED IN A TRAGIC EVENT WHICH CAUSED THE DEATH OF A FIVE YEAR OLD BOY. THE BOARD OF PHARMACY SANCTIONED TWO PHARMACISTS FOR THE ACTIVITY AND ANYONE WOULD BE MOVED TO TEARS BY THE COMMENTS IN THE MEDICAL RECORD FROM THE BOY'S MOTHER WHICH WAS INTRODUCED AS EVIDENCE DURING THE DISCIPLINARY HEARING.

AT THIS POINT THE BOARD STAFF DECIDED TO PURSUE THE MATTER FIRST RAISED BY MR. BIGGERS WITH A RULE REQUIRING THE REPORTING OF DEATHS DUE TO DRUGS DISPENSED THROUGH PHARMACIES. AT THE PUBLIC HEARING ON THIS RULE BOTH THE NORTH CAROLINA SOCIETY OF HOSPITAL

PHARMACISTS AND THE NORTH CAROLINA PHARMACEUTICAL ASSOCIATION SUPPORTED THE PROPOSED RULE. THEY REQUESTED A PERIODIC REVIEW OF THE RESULTS AND A DIVERSE GROUP OF PHARMACISTS WERE ASSEMBLED FOR THIS PURPOSE. THIS INFORMATION WAS PUBLISHED AS PART OF OUR NEWSLETTER IN OCTOBER OF 1993 AND IS PROVIDED AS PART OF MY SUBMISSION TO THE SUBCOMMITTEE.

BOARD RULE:

- (k) The owner representative or pharmacist-manager shall report to the Board of Pharmacy information that reasonably suggests that there is a probability that a prescription drug or device dispensed from a location holding a permit has caused or contributed to the death of a patient or customer. This report shall be filed in writing on a form provided by the Board within 14 days of the owner representative or pharmacist-manager's becoming aware of the event.
- (l) The Board may not disclose the identity of an owner representative or pharmacist-manager who makes a report under Paragraph (k) of this Rule, except in connection with G.S. 90-85.36. No report made under Paragraph (k) of this Rule shall be discoverable or admissible into evidence or otherwise used in any civil action involving private parties except as provided by G.S. 90-85.36.

- October, 1993

Item 766 - Task Force Reports Results

For reasons that are well-known and not necessary to repeat here, the Board adopted a rule about two years ago requiring the reporting of deaths due to drugs dispensed through pharmacies. At that time, both the president of the North Carolina Pharmaceutical Association (NCPhA) and the North Carolina Society of Hospital Pharmacists (NCSHP) called for the formation of a task force to examine the results of this reporting rule after it had been in effect for a reasonable period of time.

After the rule was in effect for one year, the Board appointed a task force co-chaired by Bill Randall from the Board of Pharmacy and Cindy Bishop from NCSHP. Other members of the task force are Al Lockamy, Steve Dedrick, Wesley Byerly, Robert L. Crocker, Amy Brown, and Tom Thutt.

At the task force's first meeting on July 30, 1993, the members analyzed the results of the first reporting year from March 1, 1992 through February 28, 1993. The task force requested that an article concerning this topic be included in this *Newsletter*.

It is significant that of the 15 reported deaths, only one instance resulted in a hearing for a pharmacist before the Board. The message is that the reporting of a death due to a drug should not be considered a confession of wrongdoing by the pharmacist. In the majority of cases, no Board action could be justified against a pharmacist.

Several matters are of concern to the task force. Some of the 15 deaths reported during the year were due to devices. Others were deemed by Board staff not to be directly attributable to drugs, although drugs may have been a factor in the overall result. There were 10 clear-cut instances in which drugs dispensed through pharmacies actually caused deaths during this 12-month period. At least three and perhaps five of these deaths could have been prevented with patient counseling.

One surprising fact derived from this data is that over one-half of the reported cases came from the community or retail setting. This is information that the Board did not anticipate and came as a complete surprise. This figure is somewhat alarming since deaths involving retail pharmacies would naturally go unreported due to an absence of close and controlled contact with the patient.

It is worthwhile to note that some drugs deserve special scrutiny in this area. It was surprising that three of the 10 deaths reported for this time period were due, in one form or another, to procainamide. One was oral, the others intravenous, but the appearance of this compound in three out of ten deaths was certainly unexpected.

As part of the Board's overall effort during the first year, inspectors investigated deaths reported through the State Office of the Chief Medical Examiner. That office reports that each year about 100 deaths are due to therapeutic agents, which are often used for suicidal deaths. The top three drugs in this regard are imipramine, amitriptyline, and propoxyphene napsylate. These three drugs account for the bulk of deaths that are due to drugs and deemed to be self-inflicted.

One other matter deserves comment. Several instances have been reported during this first year, primarily in institutions, in which a drug was ordered intravenously at a specific strength and flow rate, and an error was made either in the strength or flow rate of a drug administered IV via infusion device. Whenever changes in drug concentration or IV flow rate occur, the potential exists for errors, and that has occurred causing deaths this year. This situation deserves the special attention of pharmacists and other personnel in hospitals, nursing homes, or other sites where intravenous fluids are commonly used.

The task force will meet regularly to determine if any trends or changes in pharmacy practice are warranted, such as counseling patients or asking patients about blood work if they are taking procainamide.

DURING THE FIRST YEAR OF THIS RULE 10 DEATHS WERE REPORTED THAT WERE DUE TO DRUGS. WE RECEIVED SOME SURPRISES FROM THIS INFORMATION. FIRST OF ALL WE EXPECTED THAT MOST, IF NOT ALL, DEATHS WOULD BE IN HOSPITALS BUT THAT WAS NOT THE CASE. DURING THE FIRST YEAR, HALF OF THE REPORTS CAME FROM RETAIL PHARMACIES WHERE WE ARE FAIRLY SURE THAT EVENTS ARE GREATLY UNDER REPORTED. THE MOST THEY MAY KNOW IS THAT THE PATIENT DIDN'T COME BACK FOR REFILLS. IN ADDITION, WE BELIEVE THAT AT LEAST THREE OF THESE DEATHS WERE PREVENTABLE WITH PATIENT COUNSELING BY THE PHARMACIST WHICH IS NOW REQUIRED IN MOST STATES BUT WAS NOT REQUIRED ON THE EFFECTIVE DATE OF THE RULE.

NUMBER	DATE REC'D	DATE OF EXPIR.	L	DRUG/DEVICE	DESCRIPTION
92-1	3/11/92	3/18/90	H	Morphine & Pump	Patient had morphine post op for 24 hrs, comatose, expired 1 mo. later; records inconsistent inconclusive
* 92-2	3/19/92	3/11/92	R	Alkeran 2 mg	Rx 6 tabs daily x 4 D, 4 refills (2X)
* 92-3	3/23/92	9/22/91	H/R	Procan SR	Leukopenia
* 92-4	4/29/92	3/26/92	R	Propoxyphene	Doctor Shopper
92-5	5/26/92	5/17/92	H	Patient Restraint	Device Malfunction - Patient Suffocated
* 92-6	6/17/92	5/8/92	R	Darvocet N-100, Darvon, Valium, Percodan, Percocet	Polypharmacy
92-7	6/2/92	5/22/92	H	Procainamide HCl	375 mg ordered, 3,750 mg administered
92-8	6/19/92	5/22/92	R	Omniflox	Market Withdrawal
92-9	7/20/92	3/27/92	R	Omniflox	Market Withdrawal
92-10	8/26/92	8/20/92	H	Procainamide	Concentration change from 500 mg/100 mL D5W over 30 min to 2 Gm/250 mL D5W, 15 mL/hr; Administered at 1st rate

92-11	8/18/92	8/1/92	R	Procardia	60 mg dispensed for 30 mg.
92-12	12/1/92	11/14/92	H	KCl	40 mEq KCl ordered in 1 L administered over 4 hrs; 40 mEq in 250 mL @ 8 P.M., 8:40 and 9:35. Patient expired approximately midnight
92-13	11/23/92	11/15/92	H	Bacteria Filter Anesthesia Device	Improperly installed filter; patient expired of Anoxia
* 92-14	12/9/92	5/7/92	R	MS Contin	Prescription 1 MS Contin; 1 Tid; Prescription 2, MSIR, 1 q hr pain; filled with MS Contin

WE WERE SURPRISED TO FIND THAT THREE OF THE TEN DEATHS REPORTED WERE DUE TO PROCAINAMIDE IN ONE FORM OR ANOTHER AND THAT ALL BUT ONE OF THE DEATHS INVOLVED FEMALES. THESE UNEXPECTED RESULTS DID NOT CONTINUE INTO THE SECOND YEAR.

AT THIS POINT OUR DATA IS THAT THERE WERE TEN DEATHS REPORTED THE FIRST YEAR, THIRTEEN THE SECOND AND WE HAVE FIFTEEN REPORTS SO FAR THIS CALENDAR YEAR. FROM THESE NUMBERS, RECOGNIZING THAT THERE IS SOME UNDER REPORTING AND WE HAVE NO DATA ON OTC DRUGS WE BELIEVE THAT ABOUT 10,000 DEATHS OCCUR NATIONWIDE FROM PHARMACEUTICALS EACH YEAR.

ONE MORE POINT DESERVES EMPHASIS. PROBLEMS NOT ONLY OCCUR WITH PRESCRIPTION DRUGS BUT ALSO WITH OVER-THE-COUNTER DRUGS. JUST LAST YEAR, FOR EXAMPLE, THERE WERE THREE DEATHS IN ONE WEEKEND IN CHARLOTTE DUE TO TYLENOL. THESE OCCURRED AFTER THE INDIVIDUALS HAD INGESTED A SUBSTANTIAL AMOUNT OF BEER AND THEN CONSUMED TYLENOL. IN CASE YOU ARE NOT AWARE OF THE SITUATION, TYLENOL WAS ONCE A PRESCRIPTION DRUG THAT WAS SWITCHED TO OTC STATUS IN THE EARLY 1960'S. THERE HAVE BEEN SEVERAL PRESCRIPTION DRUGS RECENTLY MOVED TO OTC STATUS SUCH AS IBUPROFEN AND MOST RECENTLY NAPROXEN AND MANY MORE SUCH MOVES ARE PLANNED IN THE FUTURE. THERE IS NO DOUBT THAT OUR SOCIETY FACES MORE PROBLEMS IN THIS AREA WHEN SUCH DRUGS ARE COMBINED WITH PRESCRIPTION DRUGS OR ALCOHOL.

A KEY ELEMENT FOR THE SUCCESS OF ANY DEATH REPORTING PROGRAM IS THE TRUST WHICH PHYSICIANS, PHARMACISTS, HOSPITAL ADMINISTRATORS AND OTHERS HAVE THAT THEY WILL NOT BE FED INTO A GOVERNMENT MEAT GRINDER. THERE IS A NATURAL RESISTANCE TO REPORTING SUCH EVENTS AND IT DOESN'T HELP FOR SUCH REPORTS TO GO TO A MARBLE BUILDING IN WASHINGTON SUCH AS THE ONE IN WHICH WE ARE TESTIFYING TODAY. WE HAVE NOT TREATED THESE REPORTS AS AN ADMISSION OF CULPABILITY BUT

ONLY AS AN EVENT. EACH HAS BEEN INVESTIGATED AND OF THE NEARLY 40 REPORTS ONLY ONE WAS BROUGHT TO A BOARD HEARING FOR NEGLIGENCE. THIS HAS HELPED REASSURE THE MEDICAL COMMUNITY THAT A DEATH REPORT IS NOT AUTOMATIC TROUBLE FOR THEM.

STATE AGENCIES ARE MUCH CLOSER TO HEALTH PROFESSIONALS THAN THE FEDERAL GOVERNMENT AND ARE GENERALLY MORE TRUSTED THAN WASHINGTON AUTHORITIES. I ALSO BELIEVE THAT CONFIDENTIALITY PROVISIONS HAVE MORE VERACITY AT THE STATE LEVEL. MOST STATE AGENCIES HAVE SUBPOENA POWER AND AN INVESTIGATIVE STAFF TO GATHER FACTS FOR THOROUGH AND COMPLETE REPORTS. IT IS FOR THIS REASON THAT I BELIEVE THE BEST WAY TO CONSTRUCT A REPORTING SYSTEM THAT WILL BE EFFECTIVE IS TO FUNNEL DATA THROUGH STATE AGENCIES. INFORMATION COULD THEN BE ASSEMBLED BY A NATIONAL ORGANIZATION SUCH AS THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY, THE UNITED STATES PHARMACOPEIAL CONVENTION OR THE INSTITUTE FOR SAFE MEDICATION PRACTICES.

RECOMMENDATION: IT IS MY RECOMMENDATION THAT THERE BE MANDATORY REPORTING OF DEATHS DUE TO OTC OR PRESCRIPTION DRUGS TO STATE AGENCIES, SUCH AS BOARDS OF PHARMACY OR HEALTH DEPARTMENTS, WITH APPROPRIATE PROVISIONS FOR CONFIDENTIALLY AND COMPILATION ON THE NATIONAL LEVEL. THIS INFORMATION COULD THEN BE USED TO GUIDE AND IMPROVE PRACTICE TO BETTER PROTECT THE PUBLIC HEALTH AND SAFETY.

THANK YOU FOR ALLOWING ME TO TESTIFY TODAY MR. CHAIRMAN AND I AM OPEN TO YOUR QUESTIONS.

PRESENTED BY

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Chairman STARK [presiding]. Thank you.

Well, here is the dilemma. We have got two witnesses who are in the business of collecting voluntary data and I presume represent associations that are funded privately; is that correct?

Dr. VALENTINO. In a sense.

Chairman STARK. And Mr. Work, who is funded by his State government, whose recommendation is that there be mandatory reporting of deaths due to over-the-counter or prescription drugs to State agencies. I presume he would be willing to share that information with the FDA. And I gather that that is the principal contention here that we will go through with this panel and the second panel.

So I guess I would ask each of you just to come back—I mean, I do not see any other disputes here. You think it should be mandatory, and you two gentlemen think it should be voluntary. And the only information that I got earlier is that FDA says only about 1 percent of the events are reported. And that does not sound to me like the voluntary side is getting enough.

So I am inclined—and arguably working for the government, I suspect that we do some things right; there is a difference of opinion—so Dr. Valentino and Dr. Cohen, what is wrong with the mandatory?

Dr. VALENTINO. First of all, I think the 1 percent figure probably deals with adverse drug reactions.

Chairman STARK. Yes.

Dr. VALENTINO. They are not getting reports from the professions on ADRs. But I think that even with the MedWatch program, they are very careful to say that we do not want every ADR that occurs out there. We only want the serious ones.

Chairman STARK. Well let us assume that some professional is going to determine what they want. I guess my question is: What is wrong with—we require it in many areas now, and we are not hearing any complaints that I know of from the people who are required to do it—

Dr. VALENTINO. I think—

Chairman STARK. Let us assume they would contract with you to operate the required programs, so you guys would not be out of business. So that takes that off the table. But then what?

Dr. VALENTINO. Let me just say that it is not a question of business for the USP, because we are voluntarily supporting this program, and we are a nonprofit organization, and as a matter of fact we used to operate the drug product defect reporting program for the Food and Drug Administration, and currently we are a contractor with the FDA for the medical device and laboratory product problem reporting program.

And in both of these cases, we have voluntarily—with the drug program, we gave it up voluntarily, and we are in the process of giving up the device program. So it is not a question of dollars with us; it is a question, from our perspective, of doing the right thing.

I think one of the things you have to consider is, you have to be very careful in defining what you want. To give you an example, when I showed a physician on one of our panels Representative Coyne's legislation, and he read it, and it said "prescribing" or "associated with prescribing," and he said: Does this mean I am going

to be second-guessed on all of my prescription writing? Have I written the correct drug for this patient?

And then I think you have to be very careful in defining even what an error is.

Chairman STARK. But suppose this patient croaks, and he wrote the wrong prescription? Should he not be second-guessed? Would you not—

Dr. VALENTINO. The problem is—

Chairman STARK. Wait 1 minute. Would you not want to second-guess that doctor?

Dr. VALENTINO. Yes.

Chairman STARK. OK.

Dr. VALENTINO. If you could attribute the death to the drug.

Chairman STARK. OK. That is all I—

Dr. VALENTINO. And that may be a problem.

Chairman STARK. That is what the discussion is today, is it not? Attributing deaths or the sign that this could cause a death, what I would call a serious adverse reaction. It might send you a signal.

Dr. VALENTINO. With one caveat also, that we do not know if the professions would assume—and we do not know this; that is why we asked for it to be carefully considered—whether or not it would decrease voluntary reporting where people's focus would just be on deaths and—

Chairman STARK. My guess is, when the doctor thinks he made a mistake or she made a mistake, they aren't reporting it voluntarily right now, probably because they are scared they are going to get sued. But this is a whole other issue which may or may not—you know, they are not stepping up and turning themselves in every day any more than if you drove more than 55 miles an hour getting to the airport, that you are going to turn yourself in.

We just do not do that, and I—

Dr. VALENTINO. That is a serious concern. You are absolutely right.

Chairman STARK. Mr. Cohen, why can we not do this? Go ahead.

Mr. COHEN. First of all, I would like to just say that our focus has not been on that type of situation that you just described, the poor choice of a particular agent.

What we focus in on is human error in the actual use of the drug product usually, or it could be a practice—

Chairman STARK. Somebody swallowed it instead of injecting it?

Mr. COHEN. Right. In these situations, I think it is really important to understand that we do not need thousands of reports of a particular problem. In fact, one of the real concerns we have, as I mention in my testimony, with the required reporting is that this would not actually lead to the reporting of potential errors.

That is where we need to stop the problem. The first time a pharmacist or nurse sees a bad package or a bad label, we want to hear about it, so we can do something about it now, not wait to accumulate 1,000 deaths or 60 deaths or whatever it is.

And we do that. In fact, you know, we could react to one or two situations, and, in fact, people do follow through. So I think that is very important.

We do not need the numbers to do something like that.

Chairman STARK. Well, would the numbers necessarily get in your way?

Mr. COHEN. Not necessarily, no. In fact, I would say that we have absolutely no problem with increasing the numbers of reports, so long as it does not interfere with this voluntary effort. We want to encourage that.

Chairman STARK. Let us go a step further. It seems that whether people like it or not, we are headed toward some more unified billing and recording of procedures, whether that is for private insurance companies, and that—there seems to be some agreement on—I do not think there was any partisan disagreement—that we need to go to uniform reporting and perhaps toward uniform billing forms.

And much of this—and I would presume that in the pharmaceutical industry we have some indication in some States where they require tracing of prescriptions—they have got electronic tracing of prescriptions now for schedule I and II drugs, at any rate—and I do not know that we have heard any objections to that.

It does not seem to me to be much of an extension of this simplification process to require, when it is called to people's attention that they report it.

And you are saying you are not sure it is necessary, if I understand what you are saying, but you do not see that it is going to cause you any harm.

Mr. COHEN. Numbers in themselves do not mean anything. It is what is done with the information that is important.

Chairman STARK. Well, now, Doctor—

Mr. COHEN. And by the way—excuse me for interrupting—the major concern that we have is that if the information goes to the government, what can be done with it?

Of course, internally and externally, they can work individually with the drug companies. But what types of educational efforts can be performed? Can they take a picture of the product, blast it in the media, you know, and that kind of thing.

Chairman STARK. Oh, no. I think the government from time to time—look, when some kook was putting poison in aspirin or whatever the hell he was poisoning someplace, the recall of some products from shelves has worked pretty well. Nobody else does it. There is some tracing of tainted products that the government—if they do not do it well enough, there is not anybody else who does it all; let us put it that way; so that except for—in Pennsylvania recently, we do not do a bad job of supervising aircraft maintenance and training of pilots. Nobody else will do it. The airlines sure will not do it, if we do not require it.

So, you know, we are the only people around who arrest drugdealers. You know, we do not maybe do the best job in the world.

Mr. COHEN. I think it is important to point out also that, you know, it is not just the labeling and the packaging issues. It is the practicing issues as well.

Chairman STARK. It is training; it is—

Mr. COHEN. And I think that is best handled by the professions.

Chairman STARK. No quarrel there. I do not know that that is the quarrel. It is just that the issue seems to be some uniform reporting here.

And, of course, we got into this discussion a lot in the last 2 years about—you know, as I said, we do not write restaurant reviews in this business. We write laws or rules. Some people even call them mandates.

Now for us to give out a lot of advisory opinions would be more of a waste of our time than now.

So the issue is: Is this something worth focusing attention and setting up a uniform and reliable data collection process?

And I think you both agree that it is. You seem to think it works OK as a voluntary thing.

There are those—and I will ask now Mr. Work—who think that we would benefit from requiring a more thorough or extensive, whichever, reporting system.

Mr. COHEN. Well, we would just like, you know, to see the voluntary program. As I said, there has been a natural evolution that has taken place with the reporting program. We are to the point now where we need to reach new audiences, to publicize it to even health professionals who are not aware of the program. And these are efforts that we have underway to reach these new audiences. And that will naturally increase the numbers.

Chairman STARK. We want to join in the fun with you. We want to share.

Mr. Work, what should we do? You work for the government.

Mr. WORK. Well, I work for the State government.

Chairman STARK. You are still working for the government. That is what we do.

Mr. WORK. Protect the public health and safety, that is right.

I do believe that a mandatory or required system has the most merit. Even then you probably do not get all of the information you want. At least we have not gotten to that yet, because we are fairly sure there is underreporting.

I do not see from a public health and safety standpoint how it can be argued to the contrary.

Chairman STARK. Mr. Thomas.

Mr. THOMAS. Thank you, Mr. Chairman.

I do not know that this is so much a turf argument as to whether government should do it or the private sector should do it. I hope the dispute will be over how effective a system we can set up and whether it will really work. Our purpose is not necessarily to categorize, catalog, and collect errors, but to put that information to use to make sure that whatever the error was, that it does not recur. I think there can be honest differences about what is the most effective way to do that.

My problem also is that while no one disagrees with that goal there is an attempt to bring about a different structure.

When government gets into something like this, there tends to be a bureaucratic aspect of it about which I have some concern.

One, you collect the data. Two, what do you do with it? It seems to me that the data requested in this bill goes way beyond whatever information may be useful in focusing on the error questions. You have got all this other data, and then there will be attempts

to correlate data, simply because it is collected, that may or may not be useful.

It seems to me that if you have got a problem in the packaging, and the professionals are confused that kind of information should be elevated to an immediate educational program. Sadly, if a death occurs, it should not be something that is sent in to a government bureaucracy within 10 days to be compiled with 86 other examples. There should be an all-out alert inside the professional community and, depending on what it is, to the public, especially if there is some carryover that makes sense.

So once again, it is not necessarily the number of incidents that is important, but the business of what versus why. I believe I hear the private sector people saying that if you set up the wrong structure, it may, in fact, have a chilling effect on the dissemination of critical information in a timely way when, in fact, you are trying to help, and it may hinder more than it helps.

Mr. COHEN. I think it is beyond must education. It goes far beyond that. In each of these incidents, where it is appropriate, where it does involve a package or a label, every time we contact the company, we contact FDA. We also notify the professionals. And we keep doing it until the problem is fixed.

And we have an excellent track record. In fact, I would say 10 years ago, 15 years ago, when we started this program, there were loads of problems out there where blame was put on the professional, not the company, not FDA, and they did not look at all these other factors that contributed to the error.

It is much different now. I could tell you that in almost every—I cannot think of any cases that have been brought to our attention that resulted in death or injury that have not been addressed through the voluntary program.

Things have been withdrawn from the market. Standards have been changed by USP.

Mr. THOMAS. Well, what I got out of Dr. Valentino's testimony basically is that the 1970s were the stone ages, and the 1980s were the Dark Ages, and really the 1990s is a kind of an emerging relationship, both private and public. Maybe that is the reason my colleague, Mr. Coyne, is focusing on this.

The crucial question would then be: To what extent does this bill help or hurt what is ongoing? Not whether it is necessary or not is obvious because there are all kinds of ongoing activity.

Dr. VALENTINO. That is one of our fears, is that it might have a chilling effect on what we plan to do and what is ongoing now.

I think our focus is on the error. And in an ideal system, reporting system or any kind of system, it would prevent errors from occurring, so that you do not have deaths.

And what I hear is, sometimes people are saying, well, report deaths or serious injury. Well, that may be a consequence of an error, and the focus is on that. And the error that caused it may or may not be as serious as an error that was made that was caught. And what we have to focus on are the errors that occur in the systems and find ways around them, and we want professionals to bring these situations to us, so that we can change the system.

I mean, it may be a system of uniform bar coding or something like that. And that is the sort of thing that professionals will not

report to a mandatory system, and that is what we are fearing we may not get.

Mr. THOMAS. My other concern is the problem of turf wars—the private sector is collecting data now and if the Feds start collecting it, and take away some of your mission, we create a struggle between the two.

When I read this legislation I see that section 2 denies you or excludes you from the Medicare and the State health care programs if you fail to comply. Section 2 creates some difficulty in interpreting the reporting procedures within section 2, and since the penalty is exclusion from Medicare, I think that will have a chilling effect.

And my concern is that—when and how the error was discovered, all of the specific checkoff requirements, even within doing it within 10 days. If you report it within 12 working days, is that then sufficient to trigger the mandatory exclusion aspect?

It seems to me that you have got a situation where there is clearly a problem. We need more information. I am even willing to discuss the mandatory aspect of the collection of certain aspects of it.

But what you have here is a classic bureaucratic structure. The government has all of this data, some of which may or may not be useful, which focuses on the death rather than the specific error, and with a fairly stiff penalty for some bureaucrat's belief that you did not follow the standards.

So that is my concern—not whether this is an area in which we could collect it.

Let's discuss the merits of the shared information section, section 3(d). Mr. Cohen, you used the Freedom of Information Act requirement to try to get information out of the government.

You do not believe that the shared information structure within the bill would be adequate to get the kind of data that you would prefer. You believe you would have to go to the Freedom of Information Act?

Mr. COHEN. Yes, I believe that. And, in fact, when we do get information under FOI, it is very difficult to make out what happened, and we cannot get to the practitioners that reported it, because that information is taken off the report because of confidentiality. So we really cannot ever get the full situation.

You know, a lot of times an error takes place, it could start with the doctor's pen, and yet the professional blames himself. They never look at the product or the label. They are blaming themselves in the report. You know, we have to be able to get through that.

Mr. THOMAS. Mr. Work.

Mr. WORK. If I might comment on the bureaucracy issue. As a taxpayer, I am interested in not having more bureaucracy myself. And my position is that this kind of information can be developed or can be gathered by, in our case, State agencies without any additional personnel. I would not see any additional personnel.

It should be reported to people such as USP or the Institute for Safe Medication Practices or the National Association of Boards of Pharmacy or some other group like that that already exists.

And I would only point out courteously, without trying to open up any other problems, that FDA has already determined that

these drugs are safe. And if this information is fully reported to the FDA, there may be some people in FDA that will be reluctant to say that they are not safe, having already determined that they are safe.

Mr. THOMAS. Mr. Work, I may not be as kind to you as you might think, only because I have had recent experience with the vital statistics information from States.

I had reason to pursue legislation in the area of reporting of deaths in Social Security payments. The Federal Government does not collect this information but the States do. The States seem to be somewhere jealous about this vital statistics information, to the point that they sell it to the Federal Government, and if the Federal Government does not pay for it, they do not get it.

In the meantime there are months and months of improper checks to people who have been dead for some time, only because the Federal Government does not have the information that States have.

So your argument that the States should be the repository, concerns me given my recent experience with trying to collect vital statistics for Social Security.

I am concerned that we cut down errors. I am not convinced that this particular legislation or even a mandate without a clear, working, cooperative structure is necessarily the way to go.

But I would have to tell you, Dr. Work, that I do not think putting the States in the proprietary business of having this information and then making the Federal Government go hat-in-hand to the States to get it is necessarily a solution either.

As I said, based upon my experience, I do not see that as a solution.

My concern is the relationship between a collected body of information and the ability to disseminate it in a way which solves a problem that concerns us all. We have differences of opinion about how it might be achieved. I have concerns with the specifics in this, but I have far more fundamental concerns about the data being collected either for private or for governmental reasons below the Federal level, which is then either withheld or sold to the Federal Government in its attempt to do its job. So I have some concern with the States picking up even more information.

Thank you, Mr. Chairman.

Chairman STARK. Mr. Lewis.

Mr. LEWIS. Thank you, Mr. Chairman. Thank you very much, Mr. Chairman. I am sorry that I was running late for this hearing, but I want to thank you for holding this hearing this morning.

Mr. Chairman, I also want to thank our colleague, Mr. Coyne, for sponsoring H.R. 3632, the Safe Medications Act. I think this act is very much needed.

I know Mr. Work is a supporter of some form of mandatory reporting. Some people like to call it, I guess, mandates.

This member from Georgia, I do not have any problem with mandates. They can be on the part of the States; they can be on the part of the Federal Government.

But let me just ask and raise one question here. What do you think can be done to have consumers, the patient, know more about medication errors?

Dr. VALENTINO. May I?

Mr. LEWIS. Yes.

Dr. VALENTINO. One of the things that I mentioned in my testimony is that we have prepared a series of brochures for patients and the consumer. These are available at no charge. And this one here is entitled "Just Ask and Help Prevent Medication Errors." And in this brochure, it gives directions to patients and tells them some of the things they can do to make sure a medication error is not occurring and to ask the professions, ask the pharmacist: What is this medication, et cetera; what is it supposed to do?

One of the things that the States are doing now in response to the Medicaid and Medicare legislation is, over 40 States have mandatory counseling regulations now on the part of pharmacists. Now true, this is mainly outpatient we are talking about. But pharmacists in these States are supposed to counsel patients. And I think we will be finding that as pharmacists counsel patients more, that they will be catching more errors.

I mean, if you go out there and you are dispensing the wrong drug and you start to tell a patient about it, and he or she says: Oh, wait 1 minute, I am not supposed to be getting that; we will be catching more of these errors.

So I think between the counseling and educational pieces like this, I think these are some of the things we can do to help patients help themselves.

Mr. LEWIS. How do you go about making that type of educational material available? Is it through the pharmacy?

Dr. VALENTINO. Well, if—

Mr. LEWIS. Or doctors' offices?

Dr. VALENTINO. These are distributed free of charge by the USP, if anybody writes us. We advertise these in professional journals saying that they are available. If there was a company that wanted to sponsor this and buy 500,000 or so, we usually make these available at cost, and they can distribute them to hospitals or to physicians' offices, et cetera, or if a professional association wanted it we would make them available. But that is how we would do it.

Mr. LEWIS. Mr. Cohen.

Mr. COHEN. We do cooperate with the press many times. If there is an incident, for example, we would be interviewed, and we would be glad to cooperate with the press when we are called.

We have just recently written a pamphlet that is really designed to help people in the hospital. We found that the level of intensity of hospital care might produce a higher risk perhaps than that in the community. And we are not reaching the hospitalized patient and their family members.

So we put together a pamphlet which we hope to have distributed by hospital pharmacists. It was not completed by the time I had this hearing, so I could not bring it with me. Our board asked for some revisions on it. But we will make that available.

And we are also hoping to produce a video that could be shown on hospital TV to give patients instructions on things that they can do, along with the nurses and the pharmacies, to make sure that they get the information that they need to be able to prevent them from being involved in a medication error. It will not work all the time, but it will certainly reduce the risk.

Mr. LEWIS. Mr. Work.

Mr. WORK. Yes. I believe that patient counseling by the pharmacist is a big step in the right direction, which incidentally came from the Federal Government as part of the OBRA legislation, which mandated that for Medicaid beneficiaries in most States and expanded that to include private-pay patients as well.

And our board, through the help of a pharmaceutical manufacturer, Burroughs-Wellcome, produced a 30-second TV video, public service announcement, asking the public to let their pharmacist tell them more about their drugs through patient counseling when that rule was adopted at the State level.

Mr. LEWIS. Let me ask, do you have any advice or something that you can recommend to the chairman and the members of this committee about legislation to deal with the whole question of people who cannot read?

There is an unbelievable story in the Washington Post about a person——

Mr. WORK. Yes. I have been concerned about that issue for a long, long time. And the folks at USP have responded to that issue by producing pictograms, which are helpful to people who are nonreaders as far as helping them understand prescription directions. It is a simple, inexpensive way to, when they are explained, get across prescription directions to individuals with patient counseling by pharmacists.

Mr. Congressman, the matter that you mentioned is on the front page of the Post today, and it is a touching story. And I think anybody in health care that cannot understand that needs to look at that again.

And Joe Valentino can comment on USP's response to that issue, which has been admirable, certainly among the medical community.

Dr. VALENTINO. This is not really part of our error program per se, but the USP has developed standardized pictograms, and we are in the process of developing more. These are pictures which people who have difficulty in reading can just look at and with an explanation by a professional will remember how to take their medication appropriately.

We also hope to have next year—USP is developing what we call a SIG translator. It is a device so that when a prescription is given to a pharmacist, there will be a computer program which will translate the directions for use and the precautions for medication—I think it is in 18 different languages—for the people in this country who do not speak English very well. So even if the pharmacist cannot counsel on a one-on-one basis because of the language problem, this information will be available to the patient.

And there is also a program that will place on a patient package insert for the patient a bar, a pictorial that will represent how they should be taking their medications in relation to their meals, the specific times that they eat, and will place—at their breakfast at 9 a.m.—that symbol there.

And so we are working on this problem to make sure that patients take their medications appropriately.

Dr. WORK. If I might just add one more comment, this issue is not limited just to people that are in—such as the one described on the front page of the Post today.

The Literacy Society states that there are 26 million people in this country who are nonreaders, and these are people who do not read prescription labels and do not read OTC labels, not because they do not want to, because they just do not.

Mr. LEWIS. Thank you. Thank you, Mr. Chairman.

Chairman STARK. Mr. Coyne.

Mr. COYNE. Thank you, Mr. Chairman.

I would like to ask each of the panelists if any data has been collected since the establishment of the mandatory program in New York and North Carolina that indicates that there has been a decrease in the number of voluntary statements about misuse?

Dr. VALENTINO. I am not aware that we have studied that matter, no.

Mr. COHEN. I cannot say that the data is valid, because we talked to the people up in Albany about that, and they cannot tell us that it is valid. We do not know the extent of the compliance with the reporting.

But I will tell you this. The first statistics we got, I believe—you cannot quote me on this, but I will check it and get back to you—1989, and it depends on how you define “death.”

There was something on the order of 26 to 30 deaths reported, and it is required there in New York State. We asked them recently if they would, you know, give us more recent data. And using the same massaging of the data to get the deaths out, we saw that there was a drop down to 18, 16, 19, 14, I believe, over the last several years, going, I guess, as close to mid-1993. But again, I cannot by any stretch of the imagination tell you that this is valid data.

Mr. COYNE. They have increased?

Mr. WORK. We started with 10, then went to 13 the second year and we are at 15 now. This year, which indicates we should probably have—if it goes at the same rate, we should have 20 by the end of the year. So in 2 years, our reports have doubled.

Mr. COHEN. Let me just say that it is very important to ask this question, that you understand what he is including as death and what we are including as death, because it could be totally different, and what you just heard from both of us might be absolutely meaningless.

Mr. LEWIS. I do not quite understand what you mean about death, because when you are dead, you are dead. [Laughter.]

Chairman STARK. I am with you! [Laughter.]

Mr. LEWIS. So I do not quite understand.

Mr. COHEN. It does kind of sound weird, I am sure. What I am saying is, he may be—

Mr. LEWIS. I do not understand. I do not want to be confused here.

Mr. COHEN. Exactly. For example, I looked at the New York data, and one of the categories they have is deaths due to allergic reactions. Well, I would not include that as a medication error, because these are totally unpredictable in most circumstances, you know, unless the person has told you that they have an allergy to

the drug. You know, they may not have it. And they did include that. And I do not know whether he does or not; that is what I am saying.

Dr. VALENTINO. It may also include suicide data, I think, deaths due to overdose on medications.

Mr. WORK. Suicide raises another entirely different issue, which could be part of this. But just as an aside, our family, when I was young, was in the cemetery business, and we can understand what death is. It is not hard when they are dead; there is no doubt about that.

It is important, though, to understand that there is a difference between reporting deaths and reporting errors. By reporting errors, it is really, in a way, a report of an admission of culpability.

And I think that is why State agencies have a function to perform here, because they have investigative ability and subpoena power to determine if there was anything really wrong with what happened or if it just happened because people die, or whether it was suicide, whether it was an accident, or whether there was some malfeasance involved. And that usually takes an investigation rather than just what is on the paper in front of you.

Chairman STARK. Dr. Valentino brings up the issue that I always used to define what is malpractice. But there is negligence. That is where the doctor asked, if you will. That is negligence. If he asked you and you did not know, that is still malpractice, but it is not negligence. And that is something that Dr. Work would like to know, that these people routinely, when they are prescribing this drug, make damn sure that they ask: Are you allergic?

So I think that this is all germane, and perhaps it is important that somebody—you all or the States that have a system, so this kind of thing does not—so we are all asking the same questions, and we are all using the same data. Then we will not have this disagreement about what kind of death is it; it is a death.

Mr. LEWIS. Mr. Chairman, I yield back the balance of my time.

Mr. COYNE. The consensus of the panel is that there is no conclusive data that indicates that there was a decrease in the number of voluntary reports since the two States went to a mandatory system? Is that accurate?

Dr. VALENTINO. I am not aware that we have those figures. I will check it, and if we do have it, I will send it in for the record.

Mr. COHEN. Just to clarify a little bit further, I may have said "definition of death"; I cannot recall if I actually said that. What I meant was "error." You know, was it an adverse drug reaction or was it an error? And I was talking about the definition for "error." And some of these are not even determined. And that is certainly a possibility.

Mr. COYNE. Dr. Work, I just want to go back over your testimony. Is it your estimate that there are 10,000 medication error deaths in the country per year?

Mr. WORK. That is right. That is an estimate. But using the data we have, assuming there is some unreporting and that there are deaths out there due to OTC drugs, over-the-counter drugs such as Tylenol. We had three in 1 week in Charlotte, in our State just last year.

Mr. COYNE. I just wanted to clarify that.

Mr. WORK. That is right. That is our estimate.

Mr. COYNE. I would just like to clear up something, Mr. Cohen. There is nothing in this legislation that would prohibit the continuation of voluntary reporting. If there is to be a mandatory system, there certainly would be no prohibition as a result of the legislation to voluntary reporting.

Mr. COHEN. That is true. What we are saying, though, is, you know, make no mistake about it. There will be costs involved; there will be—potentially there are problems that we are concerned about. We certainly would want to make sure that it was studied.

And what we are really saying is, we need to let the natural evolution of this program work toward making the program grow, reaching the audiences that we have not reached, et cetera. That is where the marbles should go at this point, because it is a very effective program, and it has had a very good track record.

Mr. WORK. And I do not have the bill, the legislation, in front of me. But I would make one suggestion from what I heard.

As I understand it, one of the levers on this is Medicare payments. I would also suggest you include Medicaid payments, because Medicare does not pay for outpatient prescription drugs at this point generally, and it would not—that would not impact community or retail pharmacies, whereas Medicaid would.

Mr. COHEN. One other important point: There is possibly a way that we could increase medication error reports through the accreditation agencies that we are working with in the health professions.

For example, if we asked the JCHO to include a standard in the same way that they do presently for adverse drug reaction reporting, a standard that would mention reporting medication errors to the USP-ISMP, there is no doubt that the number of reports we would get would increase, because the inspectors would go around to the hospitals and ask for the documentation.

JCHO, in particular, is accrediting more than just hospitals—home care agencies, other providers—and there are other agencies. There is Medicare, for example, that could make sure that the reporting is being done to USP-ISMP to get the numbers.

Mr. COYNE. Mr. Cohen, you had mentioned earlier that you did not think that collecting data and storing it in some office here in Washington would come to any positive development and I agree with that. But the intent of the legislation is to disseminate what information comes here, so that people become more aware that these incidents are taking place.

So it is not just a matter of collecting the data; it is disseminating the data after we get it here in Washington.

Mr. COHEN. I do understand that. But I do not know what we are not disseminating now about medication errors, and I do not think really that the government could do the same kinds of things with that information that we do with the voluntary program. That is why I am concerned about it.

Mr. COYNE. Well, I thank all three panelists for your testimony. Chairman STARK. Thank you, gentlemen.

And we will continue now with our second panel. It consists of Dr. Joshua A. Perper, the chief medical examiner of Broward County, Fla.; Dr. Raymond Woosley, professor of pharmacology and medicine at Georgetown University Medical Center, chairman of the

department of pharmacology; William M. Ellis, the executive director of the Pennsylvania Society of Hospital Pharmacists; and Dr. John Lione, who is a member of the board of directors of the American Association of Retired Persons.

And we welcome this panel to the committee. And before you proceed, let me recognize Mr. Coyne.

Mr. COYNE. Mr. Chairman, thank you very much. I want to welcome all four panelists, but I want to particularly welcome Dr. Perper, who used to be the coroner in Allegheny County, Pittsburgh, and a constituent of mine up until recent months. He has now taken on the medical examiner's position in Florida, and I just—

Chairman STARK. He has become a Sunbird, has he?

Mr. COYNE. That is right. And I welcome him here today.

Chairman STARK. That is proper and fitting. As we have you first on the list, Dr. Perper, we will let you lead off.

**STATEMENT OF JOSHUA A. PERPER, M.D., LL.B., M.Sc., CHIEF
MEDICAL EXAMINER, BROWARD COUNTY, FLA.**

Dr. PERPER. Thank you, Mr. Chairman. Thank you, Congressman Coyne, for your kind words. And I am very happy to see you. And I moved to Florida not because Pittsburgh and Allegheny County are not wonderful places, but somehow in the winter the climate is milder a little bit.

Chairman STARK. No commercials, Doctor.

Dr. PERPER. Mr. Chairman and distinguished members of the subcommittee, my name is Joshua Perper. I am a physician and forensic pathologist. I am also a clinical professor of pathology, epidemiology, and psychiatry, and I am currently the chief medical examiner for Broward County, Fla.

I would like to thank the committee for inviting me to testify before it on the important subject of medication errors.

As a medical examiner, I have the responsibility of determining the cause and manner of death of sudden, unnatural, suspicious, or violent death and including in those types of death a death which results from adverse medical treatment, from medical errors, or what euphemistically we call therapeutic misadventure.

Therapeutic misadventure or adverse medical incidents are preventable medical accidents which result from faulty diagnostic or therapeutic procedure, including medication errors, which are caused or facilitated by erroneous medical decisions, negligent actions, inadequate medical equipment, and confusing or mistaken packaging of medications.

Very few studies have been done to evaluate the morbidity and mortality associated with medical error, which obviously and implicitly is an important marker of the quality of medical care which is rendered to the patient.

There are two studies which are more population studies. One is an extremely important study which was done in New York State by a Harvard medical group, which has reviewed 30,000 random medical records. And this group, I believe, produced numbers which are extremely important for the consideration of this committee.

When they applied the incidence which they found of death and illness in adverse medical results, they found out that 3.7 percent

of all patients discharged from State New York medical hospitals experienced a therapeutic misadventure and that 1 percent of all of those patients—and there were 2.6 million of them—had an adverse event due to negligence.

And when they transferred this in numbers out of those 2.6 million people, there were almost 100,000 adverse events. There were about 27,000 due to negligence. There were more than 13,000 which died as a result of the adverse event.

So if you apply—if the committee applies this as somewhat of an index to the population of the United States, you are dealing not with a minor or a moderate problem, but you are dealing with a very dramatic problem which basically consists of millions of people who experience adverse medical results, and you have hundreds of thousands of people who die as a result of that all over the country.

And in a Pittsburgh, Penn. study, we found out that the annual average rate of fatal misadventure was about 2.2 per 100 hospital admissions or 4.7 per 1 million inhabitants. The New York study found 503 per 100,000.

The quality of medical care—and it is true in Pittsburgh; it is excellent—however the discrepancy cannot be accounted by anything else than inadequate notification by health care providers.

It is clear that the adequate notification is thought to be an essential element of a misadventure prevention system, which should include total evaluation of all suspicious cases likely to be attributed to therapeutic misadventure, a clear determination whether, indeed, the medical error occurred, how and what made the error possible, dissemination among health care providers of the information on the nature and mechanism of medical error, offering procedures and options to avoid repetition of error.

And although everybody, all interested parties—the patient and their family, the health care provider, the insurance company, and the public at large—have a common and undisputed interest in the recognition and prevention of medical error, there are some specific interests that interfere with the common goal.

Obviously the injured patient, and by extension his family, have an obvious interest in the recognition of the error and its control, as well as a legal interest in pursuing compensation for physical injury or death. Therefore it is clear that it is necessary to have prompt mandatory reporting of suspected medical misadventure, a confidential investigation of suspected incidents by the Department of Health, coroner, or medical examiner or other authority, the notification of patients and their families that indeed such a confirmed incident occurred, and the periodic disclosure to the medical community.

I believe that the committee should certainly consider the extension, either at this time or at a later time, of the mandatory legislation to all types of medical misadventure, because the medication misadventures account only for 20 percent of all the therapeutic misadventures which occur in this country.

Thank you, Mr. Chairman.

[The prepared statement and attachments follow:]

TESTIMONY OF JOSHUA A. PERPER, M.D.
CHIEF MEDICAL EXAMINER, BROWARD COUNTY, FLA.

Mr. Chairman and Distinguished members of the Subcommittee:

My name is Joshua A. Perper. I am a physician and forensic pathologist. I am also a clinical professor of Pathology, Epidemiology and Psychiatry and I testify in my capacity as the Chief Medical Examiner for Broward County Florida.

I would like to thank the Committee for inviting me to testify before it on the important subject of medication errors.

As a Medical Examiner, I have the responsibility of determining the cause and manner of death of sudden, un-natural, unexpected, suspicious and violent deaths. Included in those types of death are deaths resulting from medical errors, or what euphemistically we call therapeutic misadventures. Therapeutic misadventures are preventable medical accidents which result from faulty diagnostic or therapeutic procedures, including medication errors, which are caused or facilitated by erroneous medical decisions, negligent actions, inadequate medical equipment and confusing or mistaken packaging of medication.

Very few studies have been done to evaluate the morbidity and mortality associated with medical errors, which obviously constitutes a very important marker for the quality of rendered medical care.

A 1991 New York study¹ by Brennan, T.A., Leape, L.L., Laird, N.M., Herbert, L., Localio, A.R., Lawthers, A.G., Newhouse, J.B., Weiler, P.C., and Hiatt, H.H., reported an annual mortality rate of 503 per 100,000 discharges due to therapeutic misadventures.

In a Pittsburgh, Pennsylvania, 1993 collaborative study² on mortality data of the Coroner's Office, we found that the annual average rate of fatal misadventures was 2.2 per 100,000 hospital admissions or 4.7 per million inhabitants (total 63 cases) were clearly much less than that reported in the New York study.

Though the quality of medical care in Pittsburgh is excellent, this discrepancy could not be accounted by anything else than inadequate notification by health care providers. The inadequate notification of medication errors and other types of medical misadventures is well documented in the medical literature.

It is clear that adequate notification is the essential element of a misadventures prevention system which should include:

- Thorough evaluation of all suspicious cases likely to be therapeutic misadventure.
- A clear determination whether indeed a medical error occurred, how and what made the error possible.
- Dissemination among health care providers of the information on nature and mechanism of medical errors.
- Offering procedural options to avoid repetition of the errors.

It would appear that all interested parties, the patients and their families, the health care providers, the insurance companies and the public at large, have a common and undisputed interest in the recognition, awareness of and prevention of medical errors.

However, some specific group interests may interfere with the common goal. The injured patient, and by extension his family, have an obvious interest in the recognition of the error and its control, as well as a legal interest in pursuing compensation for physical injury or death.

The health care providers, both individuals and institutions, while having an interest in the recognition and prevention of medical errors, are inhibited by their concern that their professional competence and reputation may be damaged and they may be subject to costly malpractice litigation.

The insurance companies are obviously interested primarily in the reduction of their financial liability.

The public at large, basically the pool of actual and potential patients, is primarily interested in the preventive aspect of recognition of medical misadventure.

It is clear that those interests are not likely to be easily reconciled. There is a clear need for legislation, both at the State and at the Federal level, which would insure a fair resolution of this problem by requiring:

1. Prompt mandatory reporting of suspected medical misadventures, including medication errors, which resulted in substantial injury or death.
2. A confidential investigation of suspected incidents by Department of Health, Coroners or Medical Examiners, or other designated authorities. Such confidential investigation would prevent unfair damage to the reputation of health care providers by unsubstantiated claims.
3. Notification of patients and/or their families of the occurrence of a confirmed incident.
4. Periodic disclosure to the medical community of the various types and mechanisms of reported medical misadventures (while protecting the confidentiality of the involved patients and health care providers), as well as the presentation of preventive options.

During my previous tenure as Coroner of Allegheny County in Pittsburgh, Pennsylvania we drafted such legislation which was subsequently introduced in the Pennsylvania House of Representatives by Representative Tony DeLuca. I believe that a similar type of legislation at a Federal level is likely to improve significantly the quality of medical care provided to the American people.

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LIFE-THREATENING AND FATAL THERAPEUTIC MISADVENTURES

Joshua A. Perper, M.D., LL.B., M.Sc.

"There are some patients whom we cannot help;
there are none whom we cannot harm." Bloomfield,
as quoted by Edward C. Lambert in "Modern
Medical Mistakes" Indiana Univ. Press 1987

Overview:

The available literature indicates that therapeutic misadventures affect a substantial percentage of hospitalized patients, and often result in permanent disability and death. Almost all studies suggest that for a variety of reasons including fear of litigation, under-reporting of such incidents is highly prevalent.

The patients at risk are primarily elderly people in poor health and hospitalized over longer than average periods of time. Though physicians are involved in the majority of the incidents, auxiliary medical personnel are responsible for the adverse event in a substantial proportion of cases.

It is vitally important to increase both the reporting of therapeutic misadventures from the health care providers as well as to disseminate among the medical community, adequate information regarding the nature and possible prevention of adverse peritherapeutic events. Such increased reporting and educational activities may be effectively achieved through confidential professional panels and through appropriate enacted legislation.

Introduction:

In the course of history, people have come to an early realization that the administration of medical care is not free of risk for limb or life. One of the first legal codes, that of the Babylonian King Hammurabi of the second century B.C. held the provider of care strictly liable for death or injury of a patient, and provided a specific menu of quite severe penalties. A surgeon who caused the death of a patient was likely to have his fingers cut off and a nurse who mistakenly exchanged two infants had to sacrifice her breasts.

Perhaps a similar realization of the physician's limitations prompted the writers of the Talmud to issue the uncomplimentary opinion that "The best of physicians is headed for Hell".

Modern times have been more benign to the shortcomings of the provider of medical care, as society recognizes that peritherapeutic injuries or deaths are not necessarily a result of negligence and may occur without any fault on the part of the provider of care. (Lambert, 1978) The physician or other medical providers are held liable only when an injury occurs as a result of a medical intervention, there was a legal duty to provide medical care, and when the diagnostic or therapeutic action was below the accepted medical standards.

In recent years a plethora of somewhat confusing terms has been used to designate injuries related to rendering of medical care. Those terms include iatrogenic diseases or injuries, therapeutic misadventures, nosocomial diseases, side effects, medical hazards and adverse (medical) events. In addition, there are terms such as iatrogenic misadventures, peri-therapeutic misadventures, peritherapeutic accidents, medical accidents, complications of medical care and diseases of medical progress.

Some of the terms have been preferentially used in a more general sense while others have been more restricted. The following classification is designed to define more clearly the major types of injuries or illnesses associated with medical diagnosis or treatment in accordance with the generally accepted nomenclature.

Iatrogenic Diseases/Injuries:

Such conditions include iatrogenic illnesses due to conceptual errors, side effects of procedures or medication, nosocomial diseases, and therapeutic misadventures or peri-therapeutic accidents.

Iatrogenic injuries or illnesses are adverse effects resulting wholly or in part, from medical procedures or medication and which are not a direct or indirect complication of the patient's primary condition or disease.

This chapter is primarily concerned with the category of iatrogenic injuries designated as therapeutic misadventures, and in particular the fatal therapeutic misadventures. However, the following discussion of the other categories might be helpful to place the therapeutic misadventures in proper context.

Conceptual Errors Resulting in Iatrogenic Disease or Injury:

A major group of iatrogenic injuries is the result of conceptual errors or an erroneous concept in selecting a diagnostic or therapeutic procedure. The erroneous concept assumes an actual or theoretical medical benefit justifies a specific therapeutic approach. There error is failing to foresee the nature or magnitude of possible injurious effects. The famous biologist T.H. Huxley adequately defines such frustrating situations as demonstrating "A beautiful theory killed by nasty, ugly little facts." An injurious procedure due to a conceptual error is technically correctly performed according to the initial intent and in line with the general prevailing standards of medical care at that particular time. The procedure ultimately results in a cluster of injuries or fatalities which eventually prompt its discontinuance.

The failure to consider the injurious aspects of the medical procedure or medication may be a result of the intrinsic inability of medical science at a particular time to predict the adverse event, a failure to design a proper procedure for the detection of possible adverse effects of a new procedure or medication, or a predictive failure because of an excessively long interval between the rendered medical care and the injurious result.

There are many examples of iatrogenic injuries due to conceptual errors. Such examples include the antiquity honored use of blood letting as a universal remedy, the middle age and early modern times use of enema as a universal therapeutic procedure - based on the faulty theory of auto-intoxication, and the failure to observe antiseptis during surgical procedures based on ignorance of the existence of infectious microorganisms. Other examples are the indiscriminate practice of tonsillectomy - based on the failure to understand the immuno-protective role of lymphatic tissue, the radiation of the thymus in children based on the faulty concept of status thymo-lymphaticus and failure to appreciate the tumorigenic effect of irradiation on the thyroid. More recent examples of iatrogenic conditions resulting from erroneous therapeutic concepts include the exposure of premature infants to excessively high oxygen concentration which led to retrolental fibroplasia and blindness, the use of insulin coma in the treatment of the schizophrenics while minimizing the hazards of critical hypoglycemia, and the freezing of gastric ulcers without adequate controls indicating the efficacy of the procedure.

The difference between iatrogenic illnesses due to conceptual errors and side effects of a diagnostic or therapeutic medical procedure is that in the former the selected medical approach is not indicated, unsound, or inappropriate and the complicated injury or illness totally unexpected. In medical side effects the selection may be totally justified, and some or all of the side effects accepted as reasonable therapeutic trade-ins.

The difference between iatrogenic illnesses due to conceptual errors and therapeutic misadventures is that in the former as opposed to the latter, the selection of the medical care though wrong is free of technical mishaps. As long as conceptual errors are unwittingly accepted in the medical community as standard medical practice, related injuries cannot be considered an outcome of malpractice.

Side Effects of Medication or Therapy:

There are no medications or procedures which are totally free of potentially adverse effects. Side effects, however, vary greatly in nature, severity, and frequency with the particular therapeutic approach. The role of the medical care provider is to balance the therapeutic benefit versus the potential injury. "If the price is right" and the primary disease significant enough, a competent physician may be justifiably willing to accept the possible occurrence of substantial discomfort or a side effect related disability. This may occur even to the point of insisting on the continuation of the therapy in spite of persistent side effects. For example, with regard to radiation treatments of neoplasms or treatment with radiomimetic drugs, the therapist is well prepared to accept secondary side effects of anorexia, nausea and vomiting, extensive loss of hair, and marked depression of bone marrow activity with anemia and granulocytopenia.

Occasionally the side effects are delayed and unpredictable, and may result in severe disability or death. The tragic examples of congenital fetal malformations associated with the intake of the sedative Thalidomide by the mother, and the development of clear cell carcinoma of the vagina in daughters of women who took DES (Diethylstilbestrol) during pregnancy, are only two of the more well known examples.

Nosocomial Diseases:

Nosocomial diseases are diseases which develop during the hospitalization of patients. Those diseases most often result from exposure of patients, particularly those susceptible to infections, to an injurious agent more likely to be found in an institutional medical care environment.

Examples of nosocomial illnesses are infections by drug resistant hospital strains, urethral infections in catheterized patients, and infections in burn victims.

Often the source of infection is insidious and difficult to identify. For example, in some burn victims kept in a totally aseptic hospital environment, the nosocomial infection has been traced to bacteria present in the unremoved stalk remnants of vegetables served to the patient.

Therapeutic Misadventures or Peri-Therapeutic Accidental Events and Related Fatalities:

A therapeutic misadventure or a peritherapeutic adverse event is an unexpected or unexplained medical-care related injury or adverse outcome, which is not an inherent disability, side effect, or unpreventable natural complication of the involved procedure or medication, or a natural complication of the patient's initial conditions. Therapeutic misadventures are adverse effects caused by diagnostic or therapeutic procedures, excessive or inappropriately administered medication, allergy or idiosyncrasy to medication, and failure of equipment.

Under this definition, fatal therapeutic misadventures are considered as such when they are caused, wholly or in part, by a diagnostic or therapeutic manipulation which results in mechanical injury; by an incorrect, mistaken, or substandard medical procedure; by an inappropriate, mistaken, or overdose of medication; by incorrect use of medical equipment; or by the use of inappropriate, malfunctioning, defective, or inadequate medical equipment. Fatal therapeutic misadventures are also considered to occur when the death occurs during or immediately following the medical procedure and is not reasonably explained by the patient's prior condition.

On the other hand, deaths resulting from complications and/or developments of the injury or disease for which the patient sought the initial care and inherent side effects or natural complications of the diagnostic or therapeutic procedure should not be considered as therapeutic misadventures. Examples of such adverse non-accidental events include cardiac arrests occurring during a monitored stress exercise, a pneumonia developing after a surgical procedure, or agranulocytosis following treatment with chemotherapeutic agents. In contrast, therapeutic misadventures have clear accidental connotations and are subject to a medico-legal investigation.

The Investigation of Fatal Therapeutic Misadventures:

The accidental nature of the fatal therapeutic misadventures implicitly mandates their reporting to the local Coroner or Medical Examiner. For a variety of reasons, substantial under-reporting of peritherapeutic is the rule rather than the exception. Beyond under-reporting, an additional difficulty is posed by some Coroners or Medical Examiners who exempt all peritherapeutic deaths from the accidental category and therefore abstain from investigating such cases. This approach is based on the erroneous belief that accidental peritherapeutic complications of natural diseases lose their accidental coloration through the magic of the therapeutic involvement and become natural side effects which escape the forensic net. In other words, the very fact that the peritherapeutic accident occurs in the process of treating a natural condition or an injury, transforms it into a general peritherapeutic complication free of accidental connotations.

Additional factors which may prompt a disinterest in investigating therapeutic misadventures include an overprotective attitude towards medical care providers by physicians heading medico-legal offices, a belief that because the rendering of care is basically an altruistic act it should not be burdened with the label of accident and possible related malpractice litigation, an effort to avoid a confrontation with individual physicians and/or organized medicine, and a lack of financial or professional resources to perform an adequate forensic investigation and evaluation of adverse medical events.

Initial Investigation:

The investigation of therapeutic misadventures is one of the most difficult responsibilities of a medico-legal office. The initial investigation of a possible therapeutic misadventure must consider the reliability of the reporting source and whether the alleged incident is of an accidental nature. Occasionally families or their legal representative may request under the guise of a therapeutic misadventure, the medico-legal investigation of a case in which they suspect negligence.

Medical negligence cases are not necessarily accidental therapeutic misadventures. Those cases may involve such issues as misdiagnosis, delayed diagnosis, selection of inappropriate diagnostic or therapeutic procedures, failure to perform certain diagnostic tests or to adequately carry certain diagnostic or therapeutic procedures, and inadequate or insufficient medication. Such issues which are the proper subject of civil litigation are, however, not necessarily medical accidents under the jurisdiction of the Coroner or Medical Examiner. Therefore, allegations of therapeutic misadventures should in such cases, be properly rejected unless there is credible or at least reasonable evidence that a medical accident might have occurred.

It is equally common that some providers of care who report a fatality involving a suspicious peritherapeutic incident, try at the same time to minimize the significance of the incident or to argue that the occurrence of a medical accident was extremely unlikely. In this way the medical informer attempts to have the

best of both worlds: the reporting is legally made but the Coroner or Medical Examiner may be convinced to decline jurisdiction.

Once a determination has been made that a bona fide suspicious case of a fatal therapeutic misadventure is to be investigated, prompt preliminary interviews with the principals involved and the primary physician should be scheduled. Such "warm" interviews are very important as they are likely to elicit a recollection of recent, undistorted information. Also, it is strongly recommended that immediate steps be taken to secure any biological specimens which are in the custody of the provider of care such as blood samples and frozen or formalin fixed tissue.

Pertinent medical equipment and medication such as anesthesia apparatus in anesthesia related deaths, containers of intravenous blood or other infusions, intravenous tubing, syringes of recently used medications, and bottles with medication are to be obtained in appropriate cases. Hospital personnel may discard such evidence. Therefore, the importance of promptness in subpoenaing such evidence cannot be over emphasized. It is good practice to establish in advance a therapeutic misadventure reporting protocol for the medical provider. That protocol should specify the type of evidence which is likely to be requested in suspected therapeutic misadventures. For example, hospitals should be requested not to remove any intravenous lines, tracheostomy tubes or any other invasive devices from the body of the deceased, to preserve all biological samples, and to make available any extracorporeal devices or equipment which may be related to the death.

Finally, prior to the autopsy the full medical records should be subpoenaed for review. This is important because the nurses' notes may contain more information about the nature of the incident than is contained in the usually terse notes of the physician's follow up. Furthermore, the incident report and all internal investigation notes should be specifically requested. Many health facilities regard these confidential records as not being part of the file proper and do not usually include them in the submitted records.

The Autopsy:

The autopsy should obviously address the question whether the medical incident was related to the patient's death. Such focusing may require an examination of invasive devices in situ. This includes special examination for air embolism, special toxicological or immuno-serological studies, and special histochemical stains. Full and thorough documentation of gross, microscopic, toxicological, and other findings is invariably required because of possible civil litigation.

The Inquest:

The usually complex nature of many therapeutic misadventures and the details of the incident which are often murky or inadequately reflected in the medical records require an additional evaluation. That evaluation follows the completion of the autopsy and of the relevant auxiliary tests and can be made through the vehicle of an informal or formal inquest. Most Coroners and many Medical Examiners have a statutory right to subpoena witnesses and documents and to take testimony under oath during informal and/or formal inquest proceedings.

Though the Coroner's Office in Allegheny County, Pennsylvania has the legal authority to conduct both informal investigations and public formal inquests, a policy was adopted of conducting non-public inquests rather than public inquests in most cases in which a therapeutic misadventure is suspected.

The testimony in such cases is taken under oath and recorded stenographically. The witnesses are allowed to bring their own attorneys to the proceedings. The reason for such in-chamber procedures is that it is not uncommon that an alleged therapeutic misadventure cannot be substantiated. A public inquest in such cases may unfairly affect the reputation of the medical institution

or of the provider of care. The confidential nature of the investigation also prompts more reporting and cooperation from the health care providers. Furthermore, the stenographic record of the inquest is provided to the bereaved family or representatives of the estate. The stenographic record offers the bereaved family a credible picture of the events preceding and/or following the misadventure incidents and permits them to make an informed decision whether or not civil action should be contemplated.

If the initial investigation indicates gross or criminal medical negligence, a public inquest is scheduled rather than an in-chamber inquest. If it is determined that a direct or indirect, primary or secondary complication of a therapeutic misadventure caused the death of the individual, the death certificate is completed to indicate whether such cause of death was primary or contributory and the manner of death is listed as "accident".

Reporting of Therapeutic Misadventures:

The published literature is unanimous in that therapeutic misadventures are notoriously under-reported. The major reason for the under-reporting is the adverse effect of the incident on the reputation of the medical care providers and the potential threat of malpractice litigation. The longer the time interval between the incident and the death, the less the chance of reporting the incident. This is either because of a failure to relate the final complication to the medical misadventure or because a transfer to another medical facility may lose sight of the prior medical accident. Also, the fact that most victims of therapeutic misadventures are old and very ill facilitates the shifting of responsibility for the death from an accidental medical event to natural or other unrelated causes.

Nevertheless, reporting is usually forthcoming when the Coroner or Medical Examiner is known to vigorously pursue the investigation of therapeutic misadventures, when the families are aware of the incident, or when the incident is of such magnitude that it cannot be concealed. The reporting occasionally originates outside official hospital channels and may come from family, nursing or technical personnel, or other patients.

Epidemiologic Data on Therapeutic Misadventures:

Therapeutic misadventures are reported in the literature as isolated case reports, reviews of adverse events associated with various medical procedures and population studies.

Population studies may focus on a population of patients in a particular hospital, groups of patients with specific pathology or who are subjected to specific medical procedures, random samples from patient population of county or state hospitals, and peritherapeutic fatalities reported to coroners or medical examiners.

Case Reports of Therapeutic Misadventures:

Examples of isolated reports of therapeutic misadventures include reports of traumatic injuries during invasive manipulations of hollow organs, such as cardiac injuries during valve replacement surgery (Hawley, Kennedy, Pless, Gauger & Waller, 1988); ureteral injuries during manipulative or invasive procedures (Woodland, 1992); unusual surgical or medical complications, such as mediastinal emphysema secondary to dental drilling (Hunt & Sahler, 1968); preventable post-operative, life-threatening electrolyte imbalances (Arief, 1986); anesthesia related complications or deaths (Sperry & Smialek, 1986); medical equipment related injuries (Jost, et al., 1989); and injuries associated with inappropriate or excessive medication. (Hejka, Poquette, Wiebe, & Huntington, 1990)

Therapeutic Misadventures Associated With Specific Medical Procedures:

There are quite a number of studies evaluating therapeutic misadventures associated with specific medical procedures.

Limitations of space permit only the presentation of a few more salient examples.

A 1988 study done by Natali in France, reviewed 277 vascular iatrogenic injuries which occurred over a period of 24 years. (Natali, 1989) Most of the incidents (121 occurrences or 44.8%) were due to invasive procedures. These procedures included injection, perfusion, catheterization and arteriography. Of the remainder injuries, orthopedic surgery injuries accounted for 69 incidents (24.9%), general surgery for 14 (5%), and surgery for sclerosis of varicose veins for 71 cases (25.6%). In 82 instances (29.6%) the nature of the iatrogenic injury was defined as being very severe. The authors emphasized that most of the injuries were due to imperfect techniques or professional errors.

Linden et al, reported on the incidence and characteristics of transfusion errors which occurred in New York State, over a period of 22 months, from January 1990 to October 31, 1991. (Linden, Paul & Dressler, 1992) Among 1,784,600 transfusions of red cells there were 92 cases of erroneous transfusion (1/19,000 transfusions), including 54 ABO-incompatible transfusions (1/33,000 transfusions) and three fatalities (1/600,000 transfusions). In most cases, patients with an ordered transfusion received blood of an incorrect group and in several cases patients with no ordered transfusions received blood intended for another patient. The majority of the reported errors occurred outside of the blood bank. Forty-three percent of the incidents arose solely from failure to identify the patient and/or the unit prior to transfusion, and 11% from phlebotomist (blood-drawing technician) errors. The blood bank alone was responsible for 25% of the errors (wrong blood group was used or cross matched). The study (Linden, et al., 1992) also demonstrated a substantial under-reporting of transfusion related misadventures particularly those involving phlebotomy (blood drawing) and ordering. When corrected for under-reporting, the estimated true risk for transfusion errors raised to 1 per 12,000. The authors emphasized that a national application of the New York State data resulted in an estimate of 800 to 900 projected red-cell associated catastrophic errors annually in the United States.

Some of the studies have concentrated on groups of patients who by virtue of their age, illness, or injuries are particularly at risk for therapeutic misadventures. Davis et al, have analyzed the magnitude and significance of critical errors on preventable mortality and morbidity in a regionalized system of trauma care in a group of 12,910 trauma patients admitted to six trauma centers over a three year period. (Davis, et al., 1991) Critical care errors were found in 151 (23%) of all patients. Such critical care errors were identified as the cause of death in 30 (48%) of the 62 preventable deaths. Accidental toxic exposure may also occur within health care facilities. Scalise, Harchelroad, Dean and Krenzelok (1989) describes six categories of such therapeutic misadventures which were reported to a Poison Center within a twelve month period. Those categories were right patient/wrong medication, 18%; right patient/right medication/wrong dose or route, 16%; lack of patient education, 2%; proximity of potentially harmful substances to confused persons, 54%; and incorrect equipment management, 4%.

In a number of studies the data base of adverse peritherapeutic events was drawn from reports of malpractice claims related to a particular medical specialty or procedure. (Ahamed, 1992; Kravitz, 1991; Rosenblatt, 1989)

Therapeutic Misadventures in Specific Departments and Hospitals:

Data on the characteristics and incidence of therapeutic misadventures in the specific hospital populations, though obviously providing limited information, are easily available for both retrospective and prospective studies. Even so, the number of such studies both in United States and abroad is surprisingly small.

In 1963, Schimmel conducted a prospective study of hazards of hospitalization in 1,014 patients admitted to Yale University Medical Service of Grace New Haven Community Hospital in Connecticut, over an eight month period. (Schimmel, 1964) Unfortunately, the study specifically excluded any adverse reactions resulting from inadvertent errors by physicians or nurses, or post-operative complications. During the study period, the hospital staff reported 240 episodes in 198 different patients; i.e., 20% of the hospitalized patients had one or more such adverse events. The episodes were classified as adverse reactions to diagnostic procedures, therapeutic drugs, transfusions, other therapeutic procedures, acquired infections, and miscellaneous hospital hazards. The most common adverse events which accounted for 119 episodes (49.6%) were reactions to therapeutic drugs. There were 16 deaths which were determined to be related to adverse events, "though the precise causal role was difficult to establish."

In spite of the provisos, most of these deaths in the Shimmel (1964) study clearly appeared to be due to therapeutic misadventures. Such deaths include the case of a middle aged woman with cirrhosis who died with mediastinal emphysema (air infiltrating soft tissues of the chest) following a minor laceration of the esophagus during diagnostic esophagoscopy and a patient who was treated with heparin (blood thinner) and died from a massive retroperitoneal bleeding arising in a previously undiagnosed malignant kidney tumor. There was a case of a gastric esophageal balloon which ruptured producing asphyxia as well as nine fatalities associated with drug administrations including three involving digitalis (overdoses of cardiac medication). Prolonged hospitalization (averaging more than one and a half weeks) and increased severity of primary illness were identified as major risk factors of the adverse events.

A study by Steel, Gertman, Crescenzi and Anderson (1981) prospectively followed 815 patients who were admitted consecutively over a period of five months to the general medical service of a University hospital. The Steel group defined an iatrogenic illness as any illness that resulted from a diagnostic or therapeutic procedure or any form of therapy. Their definition of iatrogenic illness also included harmful occurrences (such as a fall) which were not a natural consequence of the patient's disease. The study found that 290 patients (36%) developed a iatrogenic injury. The incidents were major or life threatening in 76 cases (9%), and fatal in 15(2%). Thirty of the 290 patients who experienced iatrogenic events died as compared to only 33 of the 525 with no complications ($p < 0.05$).

Most hospital interventions leading to iatrogenic complications in the Steel study were drug related, 208 cases; followed by diagnostic and therapeutic procedures; 175 cases; and miscellaneous (including falls), 114 cases. However, in analyzing the percentage of major complications within each one of these groups, diagnostic and therapeutic procedures took the lead with 28% major complications, followed by miscellaneous with 21% and lastly by drugs with 19%. The study found that the risk factors for major peritherapeutic misadventures were older age, severity of primary illness, poly-drug exposure, and increased hospital stay (19.3 days average stay).

In a 1986 prospective study of 1,176 consecutive patients, admitted to a department of internal medicine in Barcelona, Spain, De La Sierra, et al. (1989) reported that a total of 295 (25.1%) of these patients developed 367 episodes of iatrogenic illness. The definition of iatrogenic illness was that cited in the previously discussed study by Steele, et al. (1981) i.e., "an adverse situation due to any diagnostic or therapeutic procedure, as well as those harmful events occurring during hospitalization that are not a direct consequence of the disease of the patient, but do have a specific etiology".

Though most of the adverse peritherapeutic misadventures were relatively minor, 19 patients developed life-threatening events, including two who died. Identified risk factors were being female, old, in poor general status on admission, a hospital stay longer than twelve days, intravenous catheterization, and intravenously administered antibiotics and anticoagulants. The most common incidents included intravenous catheters, 79%; drugs 9.5%; falls from bed, 5.4%; diagnostic procedures, 3.3%; and urinary catheterization, 1.6%.

In a study of 295 patients admitted to a medical intensive care unit over a period of ten months Rubins and Moskowitz (1990) reported that 42 patients (14%) experienced one or more care related complications during their stay. The patients who experienced the adverse events tended to be older, more acutely ill, had a significantly longer length of stay, and a much higher hospital mortality rate (67% v, 27%).

Statewide or National Studies of Therapeutic Misadventures:

A bibliographic search for comprehensive nationwide or statewide reporting of hospitalized patients with therapeutic misadventures revealed only two sources of data, the 1974 California Medical Insurance Feasibility Study (Mills, 1977) and the excellent studies published by the Harvard Medical Practice Study group. (Hiatt, et al., 1989)

The California study found an incidence of 4.65 injuries per 100 hospitalizations with only 17% of those due to negligence.

The more comprehensive Harvard Medical Practice Study reported much more dramatic findings. The Harvard group reviewed 30,121 randomly selected records from 51 randomly selected acute care, non psychiatric hospitals in New-York State in 1984. (Brennan, et al., 1991) This represented a random sample of 2,671,863 patients discharged from New York hospitals in 1984.

The Harvard group identified adverse events in 3.7% of the hospitalizations; and 27.6% of the adverse events were due to negligence. Although 70.5% of the adverse events were disabling for less than six months, 2.5% caused permanent disabling injuries and 13.6% led to death. Risk factors for an increased advent of adverse events included age over 65 years. People over 65 years of age were also more at risk for negligent adverse events.

Leape et al. (1991) reported that drug complications were the most frequent types of adverse events and accounted for 19% of all incidents, followed by wound infections with 14% and technical complications with 13%.

Non surgical events were more likely to be due to negligence (37%) than intra-surgical events. Diagnostic mishaps accounting for the highest percentage of negligent adverse events were: diagnostic mishaps(75%), non-invasive therapeutic mishaps (errors of omission) (77%) and emergency room incidents (70%). Errors in management occurred in 58% of adverse events with almost half of the errors due to negligence. Certain specialties (neurosurgery, cardiac and thoracic surgery and vascular surgery) were found to have higher rates of adverse events, but lower rates of negligence. (Brennan, et al., 1991)

Univariate analyses revealed that primary teaching institutions had significantly higher rates of adverse events (41%) than rural hospitals (1%). (Brennan, et al., 1991) The percentage of adverse events due to negligence was, however, lower in primary teaching hospitals (10.7%) and for profit hospitals (9.5%) and was significantly higher, in non-teaching hospitals. The percentage of negligent adverse events was highest(37%) in hospitals with predominantly minority patients (more than 80%). These results suggested that certain types of hospitals have significantly higher rates of injuries due to sub-standard medical care.

Population Studies of Fatal Therapeutic Misadventures:

A review of the pertinent literature elicited only two studies which looked in detail at fatal therapeutic misadventures. One is an eleven year study (1973-1983) from the Montgomery County Coroner's Office in Ohio. (Murphy, 1986) The other is a ten year study (1982-1992) from the Office of the Coroner of Allegheny County (Pittsburgh) in Pennsylvania. (Perper, Kuller & Shim, 1993)

The Ohio study indicated that during the entire eleven year research period, 44 fatalities reported to the Montgomery County Coroner's Office were identified as caused by therapeutic misadventures. Unfortunately, the study does not indicate the total number of admissions to the County's hospitals or the hospitals' total bed capacity so that a misadventure to admission ratio cannot be determined. However, the study mentioned that the total population of the County was 743,600 inhabitants, the yearly average of cases reported to the Coroner's Office about 2,000, and the number of cases brought to that office for examination as 809 cases. The 44 cases represented an incidence of 0.46%, out of the 9,497 cases examined during the eleven year period.

There were marked differences in the frequency of the various medical categories involved in therapeutic misadventures. Surgical events (e.g. vascular trauma, complications of tracheostomy) accounted for 36% of the cases, anesthesia for 30%, therapeutic procedures for 18%, diagnostic procedures for 14%, and drug reaction for 2%.

The Allegheny County (Pittsburgh) study (Perper, et al., 1993) identified during a ten-year study period, a total of 63 fatalities due to therapeutic misadventures. This is from a county with a population of 1,400,000 and a total hospital capacity of 9718 beds. The annual average rate of fatal therapeutic misadventures was 2.2 per 100,000 hospital admissions.

Among the 63 fatal therapeutic misadventures in the Allegheny County study, women accounted for 39 (62.9%) and men for 24 (38.1%). Afro-Americans who accounted for only 10.5% of the county's population were over-represented with 17 deaths (27.0%). More than half of the fatalities (33 or 52.4%) occurred in people 65 years of age and older, many of whom had critical clinical conditions. The survival time from the occurrence of the incident to death was variable, sixty percent survived twenty four hours or less, 17.5% survived between 24 hours and a week, and 22.2% survived more than a week.

In the Pittsburgh study most of the medical interventions resulting in death (76.2%) were therapeutic and less than one fourth (23.8%) were diagnostic. The majority of fatalities (47.6%) were caused by traumatic medical injuries, primarily perforations and bleeding caused by intra-vascular devices. Most of the remainder were due to overdose of medication (17.5%), obstruction of airways (14.3%), anaphylactic reactions (12.7%) and anesthesia deaths (3.2%). Almost all of the incidents (92.1%) occurred in hospitals, with only three occurring in nursing homes and two occurring at the patient's home.

The Harvard study reported differences in the frequency of fatal misadventures between university-related and community based hospitals with the former having double the rate of misadventure fatalities than the latter. In the Pittsburgh study all university-related hospitals reported at least one fatal case. However, six non-university hospitals, five with less than 400 beds, reported no misadventure cases during the ten year study. Within hospitals, the incidents occurred most frequently in the operating rooms (57.1%) and hospital wards (27.0%), followed by X-Ray rooms, catheterization rooms, and intensive care units.

Among the 63 fatal therapeutic misadventures, 29 (46%) were attributed to negligent conduct; the remainder were not negligent or questionable. Among the cases showing clear evidence of

negligence, 13(44.8%) were related to medication, 6 (20.7%) related to traumatic misadventures, 5 (17.2%) related to airway obstruction and 5 (17.2%) related to other causes.

Fatal Therapeutic Misadventures and Negligence:

Although a substantial proportion of therapeutic misadventures is due to negligence or malpractice, the two entities are not identical. Therapeutic misadventures may well be accidents which are beyond the control of the provider of care. That is not so in negligence.

Furthermore, it should be emphasized that while a therapeutic misadventure is often due to error, unless the error manifests as a sub-standard medical action, no case of negligence can be made. Though this may be a reasonable argument in some of the non-fatal therapeutic misadventures, in fatal therapeutic misadventures it would be difficult if not impossible to demonstrate that an error which led to the patient's death was due to less than sub-standard quality of care.

Not infrequently, cases of death due to negligence may well lack characteristics of an accident and may be a result of a judgment failure in the diagnostic or therapeutic process. Examples include a misdiagnosis in spite of adequate data, failure to select appropriate diagnostic tests or therapeutic procedures, and delay in diagnosis or treatment. This is precisely the reason why, as previously discussed, deaths associated with medical negligence do not automatically fall under the jurisdiction of the Coroner or Medical Examiner.

It should also be recalled that only a small percentage of negligent therapeutic misadventures end in civil litigation. Localio et al, investigators with the Harvard study, reported that out of their 280 patients who had adverse events caused by medical negligence, only 8 filed malpractice claims. The total number of malpractice claims among the 30,195 patient records which were reviewed in the study constituted only 47 suits. (Localio, et al., 1991)

The study indicated that the files of the Office of Professional Medical Conduct of the New York Department of Health reflected a higher fraction of medical negligence cases resulting in claims (close to 2%). The explanation for this higher percentage as compared with the Harvard Study population is due to the fact that additional claims were made in situations in which no malpractice did in fact exist.

Localio, et al., (1991) concluded that "Medical-malpractice litigation infrequently compensates patients injured by medical negligence and rarely identifies and holds providers accountable for substandard care."²⁶ The primary reason for the low rate of justifiable malpractice suits may well be a lack of awareness by the patients or their families as to the negligent medical care, either directly or by not being notified by the health care provider. Such lack of notification is not surprising in view of the literature reports previously quoted.

Other factors may also be involved the low rate of malpractice suits such as receipt of adequate health or disability insurance benefits, the will to preserve a good patient-physician relationship, or refusal by lawyers to accept on the basis of contingency fees cases which are likely to result in small monetary awards.

Furthermore, patients who sustained only minor injury may well choose to forego litigation. Obviously such reasoning does not apply to therapeutic misadventures which result in severe injuries or death. Unfortunately the Localio study did not address specifically the question of frequency of malpractice litigation in such cases.

Prevention of Therapeutic Misadventures:

A successful prevention program in regard to therapeutic misadventures requires improved reporting, quality care monitoring, identification of risk factors for the patient, identification of risk factors for the care provider, identification of risks in the medical environment, and effective educational and preventive programs

Reporting and Quality Care Monitoring:

As previously noted, the medical literature is unanimous in concluding that there is substantial under-reporting of therapeutic misadventures.

The major culprit for the under-reporting of therapeutic misadventures seems to be the secretive method by which adverse incidents in hospitals are internally handled. In most states including Pennsylvania, there are no mandatory statutory provisions requiring the reporting of non fatal medical misadventures that occur in health care facilities, regardless of how severe such incidents may be. The incident reports that are filed in such cases are neither included nor mentioned at all in the patient's regular records, and therefore may easily escape external scrutiny. Though many states require that all evaluations and treatments be accurately recorded in the patients' charts it may not actually occur. Beyond a general duty to provide adequate guidelines and to activate quality control committees, the hospital administration is often not specifically directed to monitor the accuracy and completeness of the medical records and to provide mechanisms for correction of inadequate or inaccurate entries. One should not be surprised, therefore, by the conclusions of the Pittsburgh Study that even fatal therapeutic misadventures may remain undisclosed and unreported to the local Coroner or Medical Examiner.

When comparing the results of the Harvard studies of the New York State hospital records with the Ohio and Pittsburgh studies of fatal therapeutic misadventures reported to a medico-legal system, it becomes clear that while in the Harvard study, diagnostic errors leading to therapeutic misadventure were quite common, there was only one such incident reported in the Pittsburgh study. The reason is that errors in diagnosis are usually not reported in the Pittsburgh sites, and even if reported they are likely to be refused jurisdiction by the Coroner or Medical Examiner on the grounds that such events lack an accidental coloration and are primarily errors in medical judgement open only to civil litigation. The fatalities accepted under the medico-legal jurisdiction are, as a rule, mostly due to errors in the performance of a medical or surgical procedure, overdoses of medications, or wrongfully switched medications. Even such adverse events are often not officially reported by hospitals and as the Pittsburgh study indicates, reporting from other sources (family, anonymous hospital personnel, attorneys) is not unusual. Under-reporting is more likely to occur in cases with a longer survival interval or when a patient is transferred from one medical facility to another. For other institutional medical care facilities than hospitals (e.g. nursing homes), reporting of therapeutic misadventures is usually very low if not nonexistent.

It is unquestionable that the willful non-disclosure of fatal or severely disabling medical misadventures constitutes both a violation of medical ethics and of the law. The under-reporting of fatal therapeutic misadventures is particularly onerous. It is bound to result in erroneous certification of the cause and manner of death, failure to identify highly dangerous medical procedures and to inform others about such risks, failure to identify highly incompetent health care providers, and denial of accidental death benefits and/or the right of the estate to sue for a wrongful death.

The current situation is clearly unacceptable, and therefore urgently mandates a substantial improvement in the reporting of serious and fatal therapeutic misadventures. Most pertinent studies fail to offer specific solutions and content themselves with a

general exhortation to increase quality care through increased monitoring of peritherapeutic incidents and implementation of appropriate corrective measures.

Quality Control Agencies and Therapeutic Misadventures:

The proliferation of quality care agencies in the United States did not increase substantially the reporting of therapeutic misadventures.

The major monitors of quality of care are the quality control boards of the hospitals, the State Boards of Medicine, the insurance companies, the National Data Bank, the Food and Drug Administration (FDA), and the medico-legal investigative offices (Coroner or Medical Examiner). Those are clearly disparate bodies with very different responsibilities and interests. Some are passive repositories of data; others are active participants in the preventive or corrective effort. The limitations of the quality control boards of the hospitals have been mentioned previously in this chapter. The State Boards of Medicine have a general duty of monitoring the quality of medical practice. However, most State Boards become actively involved only after complaints of reckless medical care against specific physicians.

The State Boards of Medicine receive from the insurance companies periodic "Medical Malpractice Payment Reports" which detail incidents of injury to patients for which monetary settlements were made or court awards were given. Such reports could constitute an excellent source for the identification of therapeutic misadventures. Unfortunately, few State Medical Boards have the resources or the interest to use such a large and comprehensive body of data. Furthermore, the resolution of the malpractice suits may take years and by the time the case is reported to the State Board, it may be stale both from a legal and a medical viewpoint. The data from insurance companies are highly confidential and therefore, are virtually useless from a public standpoint except for the mandatory reports mentioned above. State laws are often silent as to the reporting of therapeutic misadventures.

The recently enacted National Data Bank, mandated by federal law (P.L. 99-660, P.L. 100-93) keeps records of various penalties imposed on specific physicians for professional and/or ethical violations. These violations include medical malpractice payments, adverse licensure actions, adverse actions on clinical privileges, and adverse actions on professional society memberships. Hospitals, other health care entities, professional medical societies and insurance companies must submit reports identifying themselves as the reporting entity and the involved medical practitioners. They also must provide descriptive information on the adverse action taken or malpractice payment made. The Data Bank is confidential and releases information only to specified authorized agents. Unfortunately, the Data Bank does not compile statistical information and does not release periodic reports on the national quality of medical care. Since 1984, the FDA has required the manufacturers and importers of medical devices to report any related serious injuries or deaths. However, later Congressional hearings and reports by the General Accounting Office (GAO) and the Office of Technology Assessment (OTA), have brought to light the fact that the reporting is largely unsatisfactory. A 1986 the GAO found that "less than one per cent of device problems occurring in hospitals were reported to the FDA and that the more serious problem with the device, the less likely it was to be reported." (GAO/PEMD, 1986; Dept. Health & Human Services, 1991)

These findings prompted Congress to enact the Safe Medical Device Act (SMDA) of 1990 which became effective on November 28, 1991. The SMDA mandates both the medical device industry and the users of medical devices to report device-related illness or injuries and includes severe penalties for violators. The Pittsburgh study group adopted a similar stance in suggesting legislation mandating the reporting of therapeutic misadventures

which result in severe disability, coma, or death and providing substantial penalties for violators. Such legislation has been indeed advocated in Pennsylvania by the Allegheny County (Pittsburgh) Coroner's Office, and is currently under consideration in the PA House of Representatives. Opposition to that legislation primarily is represented by the Pennsylvania Medical Society and to a lesser degree by the Pennsylvania Hospitals Association.

Identification of the Patients at Risk:

All studies, both hospital and Coroner's Office based, mention that the major risks factors of patients to therapeutic misadventures are older age (above 65 years of age), female sex, serious or critical illnesses, and longer hospitalization (longer than 7-10 days). Also more at risk are patients who undergo invasive procedures, in particular procedures with intravascular devices, or those who underwent penetration of hollow organs.

The increased risk of the elderly may be largely explained on the basis of the biological frailty and decreased resistance to injury and disease. However, one cannot exclude the possibility that their care is perhaps less attentive or more indifferent.

Identification of Risk Factors for the Health Care Provider:

Most studies do not specify the characteristics of the providers of care involved in therapeutic misadventures. The Pittsburgh study found that among the individuals who initiated the fatal therapeutic misadventures, 68.3% were physicians, 27% nursing staff, and 4.8% the patients themselves.

Interesting questions about the personal or professional traits of the health care providers involved in therapeutic misadventures still remain unanswered. How do factors such as their personalities, family status, health condition, graduating medical school, residency program, medical experience, and tendency for recurring episodes relate to an increased risk of getting involved in a therapeutic misadventure incident in general and in a negligent adverse event in particular.

Table I refers to some of the characteristics which may be observed in some of the care providers involved in therapeutic misadventures.

[INSERT TABLE I]

The list is written in a somewhat light vein, but all prototypes were sketched from observing a much more sobering reality. The following incidents may exemplify some of such professional or personality characteristics which are likely to result in therapeutic misadventures, often with a strong negligence character.

In one case, a registered nurse, six months out of school, erroneously gave a patient an intravenous infusion of a feeding liquid mixture which is supposed to be given only orally or through a gastrointestinal tube. The patient died within a couple of minutes with innumerable emboli of fat and vegetal fragments which clogged the capillaries of the lungs and brain.

In another case the patient, an old woman, was known to be allergic to penicillin and a warning was recorded in her chart. By error, a house physician ordered a shot of penicillin. Shortly thereafter, the doctor realized his error and canceled his instructions. Unfortunately by that time, the order was taken by a floor nurse. On arriving in the patient's room with the fateful loaded syringe, the nurse was asked by the patient whether she is to be given penicillin. The patient told the nurse that if she was to receive penicillin she would die. The nurse believing that "the doctor knows better" injected the penicillin in spite of the patient's protests. The patient died within minutes of anaphylactic shock.

It should be emphasized that in some cases the therapeutic misadventure is virtually unpreventable and occurs by no fault on the part of the health care provider. For example, during a coronary artery catheterization, a fracture of an arteriosclerotic plaque with atheromatous embolization, a local mural dissection, or a perforation of a severely arteriosclerotic vessel may be absolutely unpreventable. Under such circumstances, if the procedure was medically indicated, no reasonable case for negligence can be made. Similarly, therapeutic misadventures due to defective medical products cannot be blamed on the provider of care unless the latter adds his own contributory negligence.

Identification of Risks in the Hospital Environment:

Some of the major risks in the hospital environment include the necessary regimentation in the distribution of medicines, the use of numerous medical devices, and the impersonal relationship between certain health care specialists and the patient. As a result unless strict checking procedures and periodic quality control are in place, serious errors may occur in identifying the patient who is to be subjected to an indicated medical procedure. Withholding therapy from the appropriate patient or administering therapy to the wrong patient may result in serious injury or death.

Table II illustrates three cases in which the misidentification of patients scheduled for blood transfusions resulted in death.

[INSERT TABLE II]

It should be emphasized that misidentification errors may well be caused by physicians and not only by auxiliary health care personnel. There are sporadic incidents of physicians confusing one patient with another and ordering the wrong medication, and operating on the wrong person or on the wrong side of the patient's body.

Sometimes the error of the provider of care is facilitated by inadequate labeling of medication or defective or outdated medical equipment. For example, in the Pittsburgh study two episodes of death due to overdoses of lidocaine were due to the fact that the involved nurses mistakenly used the medication bottle with the higher dose, which had an identical packaging appearance as the lower dose. The only difference in labeling was the different concentration. Obviously, adequate preventive strategies can be easily developed to avoid such accidents.

Education and Preventive Programs:

The dissemination of detailed information among health care providers as to the nature and pathogenesis of therapeutic misadventures, particularly of those serious enough to result in disability or death, is essential to any effective preventive efforts. Unfortunately at the present time, the secrecy with which such incidents are handled within the medical care institution obviously impedes the educational effort. As a result of this communication failure, the same type of adverse event may reoccur repeatedly in different health care facilities.

When for one reason or another a particularly dramatic peritherapeutic accident becomes publicized in the media, it is not unusual to see hospital representatives come forward with most unreasonable explanations which deny the advent of that therapeutic misadventure in their facility. For example, in the case of a newborn who developed severe birth anoxia and subsequently died because the mother was erroneously subjected during delivery to a large overdose of pitocin, a well qualified medical expert stated to the press that the death could not be due to pitocin because pitocin is not a drug but an internal hormone, and as such is innocuous.

In another instance, an elderly woman sustained an intestinal perforation in a vehicular accident due to a tight safety belt. The emergency room examination, testing, and record were clearly deficient and the patient was released prematurely to her home where she collapsed 2 days later with peritonitis. A laparotomy revealed a single intestinal perforation with adjacent hemorrhage and otherwise a normal structure. The medical administrator of the involved facility announced unabashed to the media that the perforation was not due to the accident but to a spontaneous bursting of the intestines due to overeating in a patient who had some abdominal adhesions from prior surgery.

Improving Reporting:

A number of strategies may be devised in order to deal with the reluctance to report serious or fatal therapeutic misadventures. One strategy is the demonstration of a persistent and clear interest by responsible public agencies in the investigation of accidental peritherapeutic deaths. For example, the Pittsburgh study indicates that the progressively increased reporting of total therapeutic misadventures in the study area was at least in part attributable to the awareness of the local providers of care to the manifested interest and scrutiny by the Coroner's Office which is charged under the law with the investigation of unexplained, suspicious or accidental deaths.

A second strategy is the formation of a therapeutic misadventures panel representing all regional health care institutions. The Allegheny County Coroner's Office has created such a panel which is open to representatives of all hospitals in the area. Following the completion of the investigation by the Coroner's Office, the panel periodically receives a detailed report on the therapeutic misadventures which occurred over a specific period of time. The deliberations of the panel are confidential. The reports do not disclose the names of the patients, of the facility where the incident occurred, or of the providers of care involved. The panel discusses possible alternatives for preventing such episodes in the future and following its deliberations, a list of alternative strategies for preventing different types of therapeutic misadventures is mailed to all health care institutions in the area. Similar panels may be established under the aegis of other agencies or associations and may evaluate an even wider range of peritherapeutic incidents.

A third strategy is statutory mandated notification of serious or fatal therapeutic misadventures by hospitals and individual health care providers to the State Board of Health or Medicine. The statutory directives mandating health care providers to notify state health agencies of serious or fatal therapeutic misadventures should be coupled with provisions requiring the State Board of Health or Medicine to compile annual or semi-annual reports of all such incidents. The reports should also indicate how the incidents occurred, what are the possible reasons, and how they may be prevented.

DETECTION OF FATAL THERAPEUTIC MISAVENTURES BY AN URBAN MEDICO-LEGAL SYSTEM

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ABSTRACT: Very few population-based studies have evaluated fatal therapeutic misadventures, in particular the adequacy of their detection. We therefore assessed the adequacy of the reporting and detection of fatal therapeutic misadventures in an urban setting medico-legal system. The Coroner's files and the related hospital records were reviewed as to the circumstances of the incidents and the adequacy of notification by the care providers in Allegheny County, Pennsylvania, for the period of January 1, 1982 through December 31, 1991. The annual average rate of fatal misadventures was 2.2 per 100,000 hospital admissions or 4.7 per million inhabitants (total 63 cases). The survival time from the occurrence of the misadventure was within 24 hours in 60% of the cases. University-related hospitals had double the rate of misadventure fatalities (118.2 per 100,000 beds per year), compared to that in community-based hospitals (53.9 per 100,000 bed per year). In more than half of the cases, the hospitals reported the incidents within an hour from the pronouncement of death, 28.6% within five hours, and 19% after more than five hours. In 10 cases (15.9%), the notification by the hospitals was clearly deficient in determining the manner of death. In a few cases, the incident was initially reported by the relatives, by the hospital pathologists, or by the media.

A high likelihood of under-reporting of fatal misadventures to the medico-legal system is substantiated by comparing with the results reported by others. The possible measures to increase the monitoring and reporting, and to reduce the related mortality are further discussed.

KEYWORDS: fatal, therapeutic misadventure, under-reporting.

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Fatal therapeutic misadventures are primarily reported in the medical literature as case histories,^{1,2,3} limited hospital series,^{4,5} or as risk studies associated with specific medical conditions, procedures, or medications.^{6,12}

Very few population-based epidemiological studies have addressed the problems of therapeutic misadventures in general, and fatal misadventures in particular.^{13,16} This is not because of the fact that therapeutic misadventures are a rare source of injuries in the world of modern medicine. Rather, the opposite is true.

Most observers would agree that the powerful medical armamentarium available to the modern physician, the complexities of combined administration of multiple and potent medications, the multiplicity of the modern invasive techniques from coronary catheterization to laparoscopy surgery, the increase in size of hospitals to medical factory dimensions, the often impersonal character of medical care in large medical facilities, the increase in size of a geriatric population of patients who are more susceptible to medical injuries, and the effort to reduce hospital stays, are all factors which tend to increase the number of fatalities associated with medical care.

The present study was intended to determine the incidence and characteristics of fatal therapeutic misadventures in an urban setting, to evaluate the adequacy of the reporting and detection capabilities of the related medico-legal system, and to suggest ways designed to improve the monitoring and control of medical care related mortality.

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Methods:

Study Population:

Allegheny County is located in Western Pennsylvania, and has a population of approximately 1.4 million, including the City of Pittsburgh, with a population of 370,000. The area has 30 acute care hospitals, with a total of 9,718 beds, including 1,931 beds at the University Medical Center and 592 beds at Children's, Eye and

⁴Women's Hospitals, which are directly related to the University Center. Most of the hospitals have

modern facilities, and some are nationally and internationally recognized for their pioneering work in the transplantation of organs, surgical emergency care, gynecological, obstetric and pediatric care, and in many other fields.

Under the Pennsylvania law (16 Purdon Statute § 1237), "any death in which trauma, chemical injury, drug overdose or reaction to drugs or medication or medical treatment was a primary or secondary, direct or indirect, contributory, aggravating or precipitating cause of death" and "operative and peri-operative deaths in which the death is not readily explainable on the basis of prior disease" are to be investigated by the Office of the Coroner. The purpose of the investigation is "to determine the cause of any such death and to determine whether or not there is sufficient reason for the coroner to believe that any such death may have resulted from criminal acts or criminal neglect of persons other than the deceased."¹⁷ To comply with the law, the Coroner of Allegheny County requires such cases to be reported to the Coroner's Office. Over the past 10 year period, from January 1, 1982, to December 31, 1991, a total of 63 fatalities were determined by the Allegheny County Coroner's Office to be medical care-related accidents or therapeutic misadventures.

The hospital records and the coroner's files were reviewed as to the circumstances and types of the incidents, the autopsy and toxicology findings, the demographic characteristics of the deceased patients, the identity of the provider of care responsible for the incident, and the adequacy of notification of fatal therapeutic misadventure by the providers of care.

We defined a therapeutic misadventure as an unexpected medical care-related injury or adverse outcome, which is not an inherent disability, side effect, or natural complication of the involved procedure or medication.

Under this definition, fatal therapeutic misadventures were considered as such when they were caused by a diagnostic or therapeutic mechanical manipulation; by an incorrect, mistaken, or substandard medical procedure; by an inappropriate, mistaken or overdose of medication; by incorrect use of medical equipment; or by the use of inappropriate, malfunctioning or inadequate medical equipment.

Fatal therapeutic misadventures were also considered to occur when the death occurred during or immediately following the medical procedure, and was not reasonably explainable on the basis of the patient's prior conditions. On the other hand, deaths resulting from inherent side effects or natural complications of the diagnostic or therapeutic procedure such as a cardiac arrest occurring during a monitored stress exercise, a pneumonia developing after a surgical procedure or aplastic anemia occurring following treatment with chemotherapeutic agents, were not considered therapeutic misadventures.

RESULTS:

Incidence of reported fatal therapeutic misadventures:

In the past decade, between January 1, 1982 to December 31, 1991, the Allegheny County Coroner's Office has identified 63 fatalities due to therapeutic misadventures, amounting to an annual average rate of 2.2 per 100,000 hospital admissions or 4.7 per million inhabitants. The total number of cases fluctuated between 1 to 7 in the years 1982 through 1989, and then increased to 9 cases in 1990 and 23 cases in 1991. (Table 1)

Characteristics of fatalities:

Among the 63 fatal therapeutic misadventures, women accounted for 39 (62.9%) and men for 24 (38.1%). Blacks, who account only for 10.5% of the Allegheny County population, were also over-represented with 17 deaths (27.0%). More than half of the fatalities occurred in people aged 65 and above, with 33 deaths (52.4%).

The survival time from the occurrence of the fatal therapeutic misadventures was variable, with the majority surviving only 24 hours or less (38 or 60.3%), including 13, or 20.6%, who survived less than an hour. (Table 2)

Characteristics of fatal misadventure incidents:

The purpose of the medical intervention resulting in death was therapeutic in more than three-fourths of the cases (48 or 76.2%) and diagnostic in the remaining one-fourth (15 or 23.8%). Most of the fatalities, 30 or 47.6%, were caused by traumatic medical injuries. The remaining fatal misadventures were chiefly due to an overdose of medication (11 or 17.5%), obstruction of airways (9 or 14.3%) and anaphylactic reactions (8 or 12.7%). In addition, there were two anesthesia-related deaths (3.2%), a death due to a mismatched blood transfusion (1.6%), a death due to a delayed diagnosis of abdominal trauma (1.6%), and a death due to combined drug toxicity (1.6%). The specific medical activity or agent involved in the fatal therapeutic misadventures varied according to the type of medical care. (Table 3) Perforations and bleeding by intravascular catheters or balloons accounted for most of the medically induced trauma (14 or 46.7%), followed by bleeding from liver biopsy and

injuries associated with thoracostomy. There were 9 deaths with peri-operative bleeding, for which the exact source of bleeding could not be specified. Misplacement of tracheostomy tubes was the most common cause of fatal obstruction of airways. The fatal anaphylactic reactions were primarily induced by antibiotics and X-Ray contrast dyes. Overdose of medication included administration of excessive amounts of potassium infusions, lidocaine, morphine, oxytocin and others.

Site of occurrence of misadventures:

Almost all of the incidents (58 or 92.1%) occurred in hospitals, with only three occurring in nursing homes and two incidents occurring at the patient's home. There were differences in frequency of occurrence of fatal misadventures between University-related and Community-based hospitals, according to the size of the hospital. When hospitals with at least one fatal misadventure during the study period were used as a denominator, University-related hospitals had double the rate of misadventure fatalities than community-based hospitals (118.2 per 100,000 beds per year versus 53.9 per 100,000 beds per year). (Table 4)

All University-related hospitals reported at least 1 fatal case. However, 6 non-University-related hospitals, 5 with less than 400 beds, reported no cases during the 10 year study periods.

Within hospitals, the incidents occurred most frequently in operating rooms (36 or 57.1%) and hospital wards (17 or 27.0%) followed by X-Ray rooms, catheterization rooms and intensive care units.

Among the persons who initiated the fatal therapeutic misadventures, 43 or 68.3% were physicians, 17 or 27.0% were nursing staff and 3 or 4.8% were the patients themselves.

Promptness of reporting the incidents to the Coroner's Office:

In more than half of the cases (33 or 52.4%), the hospitals reported the incidents within an hour from the pronouncement of death, in 18 cases, or 28.6%, the report was made between 1 to 5 hours, in 9 cases between 6 to 24 hours and in three cases (4.8%) after more than two weeks. (Table 5) The reporting was usually made by the treating physician, by the physician who pronounced the person dead or by a hospital nurse. It should be noted that in 10 cases (17.2%) the notification by the hospital was clearly deficient either because the initial notification was misleading by omitting essential information, or by denying that the death was related to the involved medical procedure, by delaying reporting or by failure to report altogether. In the latter instance the Coroner's Office was informed of the incident by relatives, or by the hospital pathologist prior to the autopsy, by the media or by others. (Table 6)

Negligence-related therapeutic misadventures:

Among the 63 fatal therapeutic misadventures, 29 cases (46.0%) were attributed to negligent conduct, with the remainder showing either no evidence of negligence, or lacking sufficient information to make a determination. Among the cases showing clear evidence of negligence, 13 (44.8%) were related to medication, 6 (20.7%) related to traumatic misadventures, 5 (17.2%) related to airway obstruction and 5 (17.2%) to other causes. The typical examples of the negligent and non-negligent therapeutic misadventures are shown in Tables 7 and 8.

The most frequent conditions for which the medical intervention was performed were cardiovascular conditions (20 or 31.7%), including 13 cases with atherosclerotic cardiovascular disease. Other conditions which were frequently found were cancer (9 or 14.3%), and chronic or acute pulmonary diseases (9 or 14.3%). The clinical condition of the patients, prior to the occurrence of the therapeutic misadventures, was serious but stable in 34 cases (54.0%), critical in 22 (34.9%) and excellent in 7 (11.1%) patients with only minor or non-life threatening conditions.

The patients who were 65 years and above had a critical condition more frequently than the younger patients (17 or 51.5%, compared to 5 or 16.7%; p-value by Fisher's exact test = 0.01). However, the proportion of cases with negligence did not differ by the age group.

A critical clinical condition was found more frequently in the negligent cases (11 or 37.9%) as compared to the non-negligent cases (11 or 32.4%), although this difference did not reach statistical significance.

DISCUSSION:

The general characteristics of the above reported fatalities of therapeutic misadventures were consistent with those described in other studies, with the majority of the patients being older and markedly sick.^{4,5,15} This may be due at least in part to the increased morbidity in the geriatric group and an increased susceptibility to succumb to injury. Invasive diagnostic or therapeutic procedures were the most common causes of fatalities, and much more common than medication-associated deaths. Hospital-based studies have shown a similar pattern in non-fatal iatrogenic injuries.⁴

A higher rate of therapeutic misadventures was noted in University or teaching hospitals than in community-based hospitals (118.2 per 100,000 beds per year, versus 53.9 per 100,000 per year). Similar findings were reported in the Harvard Medical Practice Study in regard to therapeutic misadventures in general, though the study did not specifically report about differences in the rate of ~~fatal~~ therapeutic misadventures in particular.¹⁸ The higher rate is most likely due to the greater intensity of medical care, more complex treatments and better reporting.

The rate of fatal therapeutic misadventures in University non-affiliated hospitals differed according to the hospital size. Facilities with 400 beds or less had a higher misadventure mortality rate than those with more than a 400 bed capacity. (68.1 per 100,000 beds per year, versus 40.0 per 100,000 beds per year). The difference that is found between various types of hospitals could be attributed to the better reporting in some hospitals.

The term "therapeutic misadventure" is not identical with medical negligence or malpractice. Medical negligence is held to occur only when the injury or death is a result of a potentially preventable medical error, i.e., an injury which would not have occurred if the provider of care would have acted according to the standards of accepted medical care.

We found out that in some cases it was a difficult task to determine negligence. Cases of fatal therapeutic misadventures due to mistakenly administered medication or blood were easily assigned to negligence by their very obvious preventable nature. In many cases, the hospital records and/or the coroner's investigation, pointed to, or reliably excluded, negligence. However, the determination of the fault in fatalities due to bleeding from mechanical perforations of blood vessels or viscera, or in deaths occurring during anesthesia was much more difficult to substantiate. A perforation occurring at a weakened site of an arteriosclerotic vascular lesion permitted the timely exclusion of negligence as a factor in the absence of other information pointing to the contrary. In most vascular trauma cases, however, there was not sufficient information to either exclude or confirm negligence. None of the fatalities could be directly assigned to equipment failure or faulty equipment design. However, the overdoses of Lidocaine could be traced in part to the faulty design of the commercial containers of the drug, which had a packaging appearance virtually identical in design and color for both high and low concentrations solutions, and therefore was easily confused and interchanged.

Furthermore, in a newborn death due to hypoxia because of an overdose drip of pitocin administered to the mother, during induction of labor, the death would have been prevented by the use of a more modern pitocin pump prototype, capable of shutting itself off automatically when disconnected from the electrical outlet, even while still attached to a fully open IV line.

The most important finding of our study is its substantiation of a high likelihood of under-reporting of therapeutic misadventures, including those due to preventable medical error. The increase in the number of fatal therapeutic misadventures certified by the Coroner's Office in Allegheny County in the past two years, 1990 and 1991 cannot be explained on the basis of population increase, as the population of Allegheny County has decreased in the past decade, nor by an increase in the number of hospitals or available beds. There are no indications that the quality of provided medical care has decreased, the contrary is more likely. The apparent explanation is that an increase in reporting by the hospitals, an increased scrutiny by the Coroner's Office and a number of highly publicized therapeutic misadventures, have all converged to increase the reporting and detection index. However, even at this time the reporting of such cases remains inadequate. It is very difficult if not impossible, to believe that with the many hundreds of elderly patients receiving care in nursing homes in Allegheny County there were only three fatalities due to therapeutic misadventures in nursing homes, that out of many thousands of anesthetic procedures over a decade, there were only two therapeutic misadventure deaths due to anesthetic procedures, and that hospitals with many hundreds of beds and a considerable turnover of patients, would encounter only one therapeutic misadventure in a decade. Furthermore, the fact that we identified only one fatality, related to a unjustified delayed diagnosis of traumatic intestinal perforation, in which incidentally the involved hospital denied any fault in the face of overwhelming evidence to the contrary, strongly suggests that therapeutic misadventures due to delayed or mistaken diagnosis are practically unreported to the Coroner's Office. The high proportion (17.2%) of absent or markedly flawed notifications to the Coroner's Office re-enforces the probability of under-reporting.

In the 1991 Harvard Medical Practice Study, the largest and most comprehensive study of therapeutic misadventures to date, involving the screening of a random sample of more than 31,000 hospital records, estimated among 2,671,863 patients discharged from New York hospitals in 1984, a total of 98,609 adverse events, including 13,451 fatalities, i.e., an annual mortality rate of 503 per 100,000 discharges.¹⁹ As mentioned above, our study indicated an annual average mortality rate in Allegheny County over the past decade, of only 2.2 per 100,000 admissions. Though the quality of medical care in Allegheny County is admittedly excellent, it is unlikely that it could account for the tremendous discrepancy in the respective mortality rates. The inescapable conclusion is that the under-reporting of fatal therapeutic misadventures in Allegheny County is considerable.

Other studies have found a similar rate of under-reporting. A study reporting on fatal therapeutic misadventures certified by the Office of the Coroner of Montgomery County, Ohio, with a population area of 771,000, reported 44 cases during the 1973 to 1983 period.¹⁹ Though the report does not mention the rate of therapeutic misadventures per hospital admissions or per hospital beds, the average yearly rate per 1,000,000 population can be calculated to be 5.1, a figure similar to that of Allegheny County (4.7 per 1,000,000).

The major culprit for the under-reporting of therapeutic misadventures appears to be the secretive method by which adverse incidents occurring in the hospitals are internally handled. Current Pennsylvania law does not require the reporting of non-fatal medical misadventures which occur in health care facilities. The incident reports which are filed following such happenings in hospitals or other health care facilities are secret and available only to administration officials. In some hospitals even the very existence of an incident report is not mentioned in the patient's medical record. Though state regulations require that all evaluations and treatment be accurately and completely reflected in the patient's medical records, the hospital administration is not specifically directed to ensure and correct inaccurate or misleading records, beyond a general requirement of providing adequate guidelines and activating quality control committees. Even therapeutic misadventures which end in the death of a patient may remain undisclosed and unreported to the local coroner or medical examiner. This is particularly true when the death caused by medical care is delayed, or when the involved patient was transferred from one medical facility to another. Such situations are obviously adverse to the public interest and to the rendering of optimal medical care. Though the absolute confidentiality of internal quality review procedures is clearly justifiable and beneficial to the continuous improvement of medical care, the non-disclosure of the very occurrence of the fatal or disabling medical accidents is unethical and illegal. The under-reporting of severe cases of fatal therapeutic misadventures in general, and of fatal incidents is bound to result in erroneous certification of the cause and manner of death, failure to identify medical procedures with a high risk of fatal therapeutic misadventure, lack of awareness of providers of care as to such risks, failure to identify medical personnel responsible for an inordinate or unjustified number of fatal therapeutic misadventures, and denial of accidental death benefits or the right of the estate to sue for a wrongful death.

To correct this situation, the Allegheny County Coroner's Office has proposed legislation which mandates:

- Prompt and adequate recording of therapeutic misadventures in the patient's medical records.
- Prompt notification of the State Board of Health and State Board of Medicine (within 48 hours) of disabling or fatal therapeutic misadventures occurring in hospitals and other medical care facilities.
- The State Board of Health to notify bi-annually the health care providers of the number, types and circumstances of such therapeutic misadventures, without disclosing the identity of the patients or the institution and providers involved.
- Prompt notification of the Coroner's or Medical Examiner's Office (within 8 hours) of any therapeutic misadventure which results in the death of a patient.

In order to assure its effectiveness, the proposed bill imposes a variety of fines and penalties on violators.

We believe that under-reporting is not unique to Allegheny County and that other regions of the country should also consider similar educational and legislative measures designed to increase the monitoring and reporting of therapeutic misadventures and to reduce the related morbidity and mortality.

Since 1984, the Food and Drug Administration (FDA) has required the manufacturers and importers of medical devices to report device-related deaths and serious injuries. However, in the past years reports by the General Accounting Office (GAO), the Office of Technology Assessment (OTA) and the Congressional hearings have shown that this reporting is unsatisfactory.

A 1986 GAO study found that "less than one per cent of device problems occurring in hospitals were reported to the FDA and that the more serious problem with the device, the less likely it was to be reported".^{20,21}

These findings prompted Congress to enact the Safe Medical Device Act (SMOA)(1990), which became effective on November 28,1991, and under which both the medical device industry and the users of medical devices must report device-related illness or injuries, and includes severe penalties for violators. Though obviously such legislation will greatly assist in the detection of disabling and fatal therapeutic misadventures, it is not exhaustive enough, and will require supplementation by state laws more specifically oriented towards the detection and reporting of significant medical care accidents.

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TABLE 1
FATAL MISADVENTURES ALLEGHENY COUNTY CORONER'S OFFICE 1982 - 1991

YEAR	NUMBER
1982	1
1983	3
1984	2
1985	7
1986	4
1987	3
1988	6
1989	5
1990	9
1991	23

TABLE 2
TIME PERIOD (HOURS) BETWEEN MISADVENTURE AND DEATH

TIME INTERVAL	NUMBER	PERCENTAGE
< 1	13	20.6
1 - 5	14	22.2
6 - 24	11	17.5
25 - 168	11	17.5
≥ 169	14	22.2
TOTAL	63	100

TABLE 3
TYPE OF AGENT BY SELECTED MISADVENTURE TYPE

TRAUMATIC:		
Catheter/Balloon	14	46.7%
Liver biopsy	3	10.0%
Thoracostomy tube	3	10.0%
Electrode of pacemaker	1	3.3%
Other post-operative bleeding	9	30.0%
Total	30	100.0%
OVERDOSE OF MEDICATION:		
Potassium	3	27.3%
Lidocaine	2	18.2%
Morphine	1	9.1%
Oxytocin	1	9.1%
Other	4	36.4%
Total	11	100.0%
ANAPHYLACTIC REACTION:		
Antibiotics	3	37.5%
Contrast material for radiology	3	37.5%
Other	2	25.0%
Total	8	100.0%
OBSTRUCTION OF AIRWAY:		
Tracheostomy tube	4	44.4%
Gastric tube	1	11.1%
Other	4	44.4%
Total	9	100.0%

TABLE 4
FATAL MISADVENTURES BY UNIVERSITY AFFILIATION
AND SIZE OF HOSPITAL*

UNIVERSITY AFFILIATION	NUMBER OF BEDS	AVERAGE ANNUAL RATE PER 100,000 BEDS
YES	≤ 400	117.0
	> 400	120.1
	ALL	118.2
NO	≤ 400	68.1
	> 400	40.0
	ALL	53.9
* INCLUDES ONLY HOSPITALS WHICH REPORTED AT LEAST ONE FATAL MISADVENTURE		

TABLE 5
TIME PERIOD (HOURS) BETWEEN THERAPEUTIC MISADVENTURE DEATH
AND REPORT TO CORONER

TIME INTERVAL	NUMBER	PERCENTAGE
< 1	33	52.4
1 - 5	18	28.6
6 - 24	9	14.3
≥ 25	3	4.8
TOTAL	63	100.0

TABLE 6
HOSPITAL'S OMISSION OF NOTIFICATION TO CORONER

CASE #	AGE	CIRCUMSTANCES OF DEATH	NOTIFICATION
90-0903	41	Neck compression by hematoma post-surgery for cervical disk	Family
91-1679	77	Lung perforation with bleeding by chest tube in patient with pneumonia	Hospital pathologist asked (after completing autopsy) how he should sign certificate
91-1768	72	Lidocaine overdose in patient with arrhythmia	Body released to funeral director Notification by hospital 24 hours later
88-2222	74	Bowel injury during lysis of pelvic adhesions	Hospital pathologist 24 hours later
88-711	52	Mislabeled blood transfusions of patient with diabetes chronic renal disease and ASCVD	Consultant pathologist performing private post after review of hospital records
89-0968	69	Perforation of heart by thoracotomy tube in patient with bronchopneumonia emphysema and ASCVD	Family
89-0726	64	Perforation of carotic artery during angiography for CVA	Physician reported natural disease due to ruptured aneurysm Hospital pathologist called before post and relayed events
88-4202	60	Bleeding from liver biopsy	Physician reported death but stated that bleeding was not connected to death
91-2108	24	Uncontrolled bleeding during tonsillectomy	Family
91-1857	4 days	Newborn died of hypoxemia because of pitocin during induced labor	Notification by transfer hospital pathologist Incident not reported in records of occurrence hospital

TABLE 7
TYPICAL EXAMPLES OF NEGLIGENT THERAPEUTIC MISADVENTURES

CASE #	AGE	PRIMARY CONDITION	CAUSE OF DEATH	CIRCUMSTANCES	NATURE OF NEGLIGENCE
84-0666	80	Paraleptic ASCVD	Massive Interstitial Emphysema	O ₂ perfusion tube left in anaerobic wound	Forgetting to remove tube in time
86-1374	52	Surgery for insertion of metal knee prosthesis	Asphyxia	Obstructive plastic airway device	Forgetting to remove the device after surgery
86-0114	69	Septicemia	Anaphylactic shock	Injection of penicillin	Administering the medication mistakenly, while failing to check the record for known penicillin allergy. Failing to heed the protest of patient that she is allergic to penicillin
86-2049	7 mos	Acute leukemia	Fluid overload	Intravenous administration of K/D50	Failing to regulate the rate of intravenous infusion
88-0391	82	Acute myocardial infarction	Potassium overdose	Intravenous administration of potassium	Failing to regulate the rate of intravenous infusion
88-0711	52	Diabetes Mellitus Chronic Renal Failure ASCVD	Fatal transfusion reaction	Blood transfusion for anemia	Failure to match blood bag to patient when bags arrived simultaneously to ward
90-1428	61	ASCVD Arrhythmia	Lidocaine overdose	Administration of lidocaine for arrhythmia	Mistakenly using a lidocaine bottle of 2000mg., instead of 100mg.
91-1857	4 day	Hypoxemic shock	Pitocin overdose	Administration of pitocin to induce pregnancy	Pitocin pump disconnected from electrical outlet, but was not shut off

TABLE 8
**TYPICAL EXAMPLES OF NON-NEGLIGENT
OR UNDETERMINED THERAPEUTIC MISADVENTURES**

CASE #	AGE	PRIMARY CONDITION(S)	CAUSE	CIRCUMSTANCES	JUSTIFICATION
82-0684	72	ASCVD Septic Infarct	Hemopericardium due to myocardial rupture	Perforation of heart by pacemaker wire	Easily ruptured infarcted myocardium
91-2825	75	ASCVD	Hemopericardium due to perforated coronary artery	Perforation of coronary artery during angioplasty	Rupture occurring during atherectomy
87-1015	78	ASCVD with old and recent myocardial infarct	Hemoperitoneum due to lacerated aorta	Perforation of aorta by balloon	Easily ruptured severely arteriosclerotic aorta
90-2717	85	Pneumonia ASCVD	Stevens-Johnson Syndrome	Allergic reaction to vancomycin	Unexpected allergic reaction

Mr. COYNE [presiding]. Thank you, Dr. Perper.

And the next testimony we will hear is from Raymond Woosley, medical doctor, chairman, Government Relations Committee, the American Society for Clinical Pharmacology and Therapeutics.

Dr. Woosley.

STATEMENT OF RAYMOND L. WOOSLEY, M.D., PH.D., CHAIR, GOVERNMENT RELATIONS COMMITTEE, AMERICAN SOCIETY FOR CLINICAL PHARMACOLOGY AND THERAPEUTICS; CHAIRMAN OF THE DEPARTMENT OF PHARMACOLOGY AND PROFESSOR OF PHARMACOLOGY AND MEDICINE, GEORGETOWN UNIVERSITY MEDICAL CENTER, WASHINGTON, D.C.

Dr. WOOSLEY. Thank you, Mr. Chairman, and distinguished committee members. Thank you for the opportunity to be here today.

I am Raymond Woosley, professor of pharmacology and medicine and chairman of the Department of Pharmacology at Georgetown University Medical Center.

Today I am pleased to appear before this subcommittee on behalf of the American Society for Clinical Pharmacology and Therapeutics. Our society represents the Nation's 2,000 trained clinical pharmacologists practicing in university medical centers, at the FDA, and in the pharmaceutical industry. The majority of our members are physicians like myself. Many are clinical pharmacists or applied pharmacologists. All have been specifically trained to evaluate the actions of drugs, both good and bad, in human beings.

We are naturally pleased to present testimony on the Safe Medications Act of 1993. The authors of this legislation are to be commended for recognizing the serious consequences that result from errors in prescribing, dispensing, and administration of drugs.

This legislation calls attention to the fact that a serious problem exists which is costing lives. We do not know how many lives are lost, but we should.

The problem has multiple causes, and we believe its solution will require a broad based approach.

Yes, we must accurately quantify the problem before we can design a systematic approach to its solution. The Safe Medications Act of 1993 will begin this process, and we encourage its passage.

The mandatory requirement for reporting is essential, as is stiff punishment for those who violate the system for personal gain.

However, the inclusion of fines for failure to report could lead to gross overreporting. Health care organizations would report all cases that could even remotely be considered as drug-related in order to reduce their financial risk. Such overreporting would overwhelm the system with noise that would make detection of real problems more difficult, if not impossible.

This is what exists today with the mandatory requirement of pharmaceutical companies to report their adverse reactions.

We believe that such fines are unnecessary and that the act will be enforceable through its plan to submit reports to certifying organizations.

There are two aspects of the act that we believe could be constructively amended.

First, a simplified reporting system alone has limited value because of the extreme complexity of most clinical cases. Deciding upon the cause of a patient's death in today's complex clinical environment is in many ways analogous to determining the cause of an airline crash.

Trained investigators must be called in to evaluate the incident onsite. They are best equipped to analyze the potential contributing factors, such as the patient's predisposing medical conditions, interactions between concomitant medications, the temporal relationships between drug actions and biologic response.

Such a complex analysis requires a team of experts with special training in medicine, pharmacology, clinical pharmacology, pathology, and clinical pharmacy.

Also the act does not contain an effective mechanism to synthesize these problems and inform health care workers of means to prevent these problems. Making information available is not enough. Numerous examples, such as the continued deaths caused by the antihistamines, Seldane and Hismanal, demonstrate that research and sustained educational efforts are required.

At present, medical educators have neither the research base nor the educational mechanisms to make this possible. The Safe Medications Act of 1993 could include such a mechanism. There already exists a potential network of professionals ready to perform the necessary analyses and the educational mission. There are currently 40 clinical pharmacology training programs for physicians in our Nation; 14 are now funded by the NIH and the FDA, but only to train a few clinical pharmacologists. They have the expertise to conduct the necessary onsite analysis, identify corrective measures, and then conduct the educational programs.

The American Society for Clinical Pharmacology and Therapeutics has endorsed a proposal to utilize these training sites as the basis for regional centers for education and research in therapeutics, abbreviated CERT. These centers would evaluate adverse drug reactions as part of their mission. CERT would be affiliated with the FDA and based in academic medical centers. Participation of the pharmaceutical industry and the USP would be strongly encouraged. But CERT should be independently funded.

CERT has been described in detail in several publications. We will submit a copy of one such article from issues in Science and Technology and request that it be included in the record.

We encourage you to incorporate a research and education mechanism such as CERT into the Safe Medications Act of 1993 as a means to address the problems that will be identified through mandatory reporting of medication and prescribing errors.

Any society that invests over \$10 billion each year to develop new chemicals for improved health should have an aggressive and independent mechanism to evaluate and improve their safety. Passage of the Safe Medications Act of 1993 would be a critical first step toward that goal.

We hope you agree and thank you for the opportunity to present this testimony.

[The prepared statement and attachment follow:]

TESTIMONY OF RAYMOND L. WOOSLEY, M.D., PH.D.
AMERICAN SOCIETY FOR CLINICAL PHARMACOLOGY AND THERAPEUTICS

Mr. Chairman, Members, Ladies and Gentlemen,

I am Dr. Raymond Woosley, Professor of Pharmacology and Medicine at Georgetown University Medical Center and Chairman of the Department of Pharmacology. Today, I am pleased to appear before this Subcommittee on behalf of the American Society for Clinical Pharmacology and Therapeutics. Our society represents the Nation's two thousand trained clinical pharmacologists practicing in university medical centers, at the FDA and in the pharmaceutical industry. The majority of our members are physicians like myself, many are clinical pharmacists or applied pharmacologists. All have been specifically trained to evaluate the actions of drugs, both good and bad, in human beings. We are naturally pleased to present testimony on the Safe Medications Act of 1993.

The authors of this legislation are to be commended for recognizing the serious consequences that result from errors in prescribing, dispensing and administration of drugs. This legislation calls attention to the fact that a serious problem exists which is costing lives. We do not know how many lives are lost and we should know.

The FDA has documented that the current system of voluntary reporting suffers from extreme degrees of under-reporting. An FDA survey of 3000 physicians in 1988 found that 57% were unaware that the FDA even has a reporting system. Over one third of the physicians surveyed had observed an adverse reaction to a drug in the prior year. Although one third of these were lethal or required hospitalization, only 5% were reported to the FDA. The FDA's new Medwatch initiative is a major step forward that will improve awareness and has simplified reporting. These improvements have already increased reporting. However, the voluntary nature of Medwatch will continue to limit its potential to fully address the problems that occur with prescription drugs.

We lack exact numbers, but we know that far too many patients are being hurt by prescriptions intended to help. The problem has multiple causes and we believe its solution will require a broad-based approach. We must accurately quantify the problem before we can design a systematic approach to its solution. The Safe Medications Act of 1993 will begin this process and we encourage its passage.

The mandatory requirement for reporting is essential, as is stiff punishment for those who violate the system for personal gain. However, the inclusion of fines for failure to report could lead to gross over-reporting. Healthcare organizations would report all cases that could even remotely be considered as drug-induced in order to reduce their financial risk. Such over-reporting would overwhelm the system with "noise" that would make detection of real problems more difficult if not impossible. We believe that such fines are unnecessary and that the Act will be enforceable through its plan to submit reports to certifying organizations, such as the Joint Commission for the Accreditation of Health Care Organizations. Healthcare providers, who are non-compliant could be readily identified during the credentialing process and brought into compliance through established disciplinary procedures. Yes, we need a mandatory reporting system but one that gathers the most valuable information and has the least noise.

As clinical pharmacologists, we are pleased that the bill will include all serious drug reactions. Deaths due to medication errors are only the tip of an enormous "iceberg" that surrounds the use of medications in our nation. Many more problems are caused by poorly informed good intentions than by honest mistakes. Many side effects stop short of being lethal; they are incapacitating or permanently disabling and add unnecessary costs to overall healthcare. This is supported by recent estimates that 5% of medical admissions to hospitals are due to unwanted reactions to medications.

To complicate the problem, physician prescribing is not optimal. From the work of researchers at Harvard Medical School, we know that one in four prescriptions for the elderly is inappropriate and dangerous. According to the Physicians Insurance Association of America, prescribing errors are common. They are the second most

common cause of patient injury and malpractice claims. Why is this? Incredibly, in the nation today, information that would enable physicians to anticipate and prevent serious drug reactions is not readily available. After the second year of medical school, physicians have little, if any, opportunity for education in the basic principles of therapeutics and how to prevent drug side effects. For the average physician, two-thirds of the drugs they prescribe were developed after they completed medical school.

To make matters worse, very little research is conducted to study adverse drug reactions. There is no economic incentive for pharmaceutical companies to systematically study and publicize the adverse effects of their drugs. Federal research grants for these studies are almost nonexistent. These are but a few of the factors endangering the patient about to receive a prescription drug.

There are two aspects of the Act that we believe could be constructively amended. First, a 'simplified' reporting system has only limited value because of the extreme complexity of most clinical cases. Deciding upon the cause of a patient's death in today's complex clinical environment is, in many ways, analogous to determining the cause of an airline crash. Trained investigators must be called in to evaluate the incident on-site. They are best equipped to analyze the potential contributing factors such as, the patient's predisposing medical condition, missed diagnoses, associated surgical procedures, interactions between concomitant medications, the temporal relationships between drug actions and biological response. Such an analysis requires a team of experts with special training in medicine, pharmacology, pathology, clinical pharmacology and clinical pharmacy. A short report completed by an untrained healthcare provider or administrator will only create questions, not provide answers or even an opportunity to understand the problem.

The Act does not contain an effective mechanism to synthesize problems and inform healthcare workers of means to prevent problems. Making information available is not enough. Numerous examples, such as the continued deaths caused by terfenadine (Seldane) and astemizole (Hismanal), demonstrate that research and sustained educational programs are required. Medical educators should be able to teach physicians to prescribe safe and cost-effective therapy. At present they have neither the research base nor the educational mechanisms to make that possible. The Safe Medications Act of 1993 could include such a mechanism. There already exists a potential network of professionals ready to perform the necessary analyses and the educational mission. There are currently forty clinical pharmacology training programs for physicians in the nation. Fourteen are now funded by the NIH and FDA, but only to train clinical pharmacologists. They have the expertise necessary to conduct the complex on-site analyses of clinical cases, identify corrective measures and then educate healthcare providers.

The American Society for Clinical Pharmacology and Therapeutics has endorsed a proposal to utilize these training sites as the basis for a new program of regional Centers for Education and Research in Therapeutics (CERT) that would evaluate adverse drug reactions as part of their mission. CERT would be affiliated with the FDA and based in academic medical centers. Participation of the pharmaceutical industry and the United States Pharmacopeial Convention would be strongly encouraged but CERT should be independently funded. These centers would conduct the needed research on marketed drugs. Unwanted and dangerous actions of drugs would be examined, especially in women, children, the very elderly and other neglected populations. The centers would also conduct educational programs to inform practicing physicians, nurses, pharmacists and the public of the relative value and safety of medications. These centers could identify problems with drugs earlier after marketing and avert disasters, not only the "thalidomides" but even the less dramatic problems that draw far less attention.

We encourage you to incorporate a research and education initiative such as CERT into the Safe Medications Act of 1993 as a means to address the problems that will be identified through mandatory reporting of medication and prescribing errors.

Any society that invests over \$10 billion each year to develop new chemicals for improved health should have an aggressive and independent mechanism to evaluate and improve their safety. Passage of the Safe Medications Act of 1993 would be a critical first step toward that goal. We hope you agree and thank you for the opportunity to provide this testimony.

RAYMOND L. WOOSLEY

A Prescription for Better Prescriptions

*Physicians cannot
remain dependent
on the drug
companies
as the primary
source
of information
about
pharmaceuticals.*

Among the factors regularly blamed for skyrocketing health care costs are the price of prescription drugs and the large profits of the leading pharmaceutical companies. As health care reformers consider universal access to care and prescription-drug benefits, measures to limit drug prices and pharmaceutical profits are receiving increased attention. Although the reality is that drug costs comprise only a small fraction of the nation's total health care budget and many of the drugs have reduced the economic impact of disease, it is still important to ask why the free-market system is not operating as it normally would to allow competition to restrain drug prices and profit margins. In theory, consumers respond to high prices by seeking less costly alternatives, spurring competition and bringing prices and profits down. However, in the case of pharmaceutical products, it is the physician, not the consumer,

who chooses the therapy. The cost of this decision is then borne by the patient or the health care insurer. As a result, the feedback loop between price information and consumer behavior is severed.

Moreover, the predominant source of detailed information about the quality and performance of drugs is the industry itself. Pharmaceutical companies rightfully pursue and publish the research

that will enhance sales. They have no responsibility to perform research designed specifically to provide physicians with unbiased information on which to base their choice of therapy. Access to this kind of information could increase competition among drugs, thereby reducing prices.

Because of the high cost of medications and the high profits of many companies, the pharmaceutical industry has come under vigorous attack by academics, politicians, and consumer groups, who have called for coercive measures that restrict physicians' choices or corporate practices. Heavy-handed command-and-control policies are likely to alienate physicians and drug companies, making cooperation and success unlikely. Current trends to change the practice

Raymond L. Woosley is professor of pharmacology and medicine and chairman of the Department of Pharmacology at Georgetown University Medical Center in Washington, D.C.

of medicine toward managed competition will increase the impact of restrictive formularies and price controls on pharmaceutical profits. However, these restrictions will also adversely affect future drug development and the quality of medical care. A more constructive approach would make better information available to physicians so that they could prescribe the most cost-effective drugs. This would enlist the support of physicians, who would be enhancing their effectiveness, and would appeal to the industry by preserving the incentive to develop and produce a wide range of effective medications.

The high cost of marketing

Prescription drugs sold in the United States are among the most expensive medications in the world. The high price of these drugs imposes a tremendous burden on many of our citizens. The poor and the elderly, in particular, often pay a major fraction of their incomes for life-sustaining medications. The American Association of Retired Persons recently reported that more than half of all Americans over age 65 have difficulty paying for their prescription drugs. Ten percent have to sacrifice on food or fuel to purchase their prescriptions.

The pharmaceutical industry attributes the high cost of drugs to the cost of research and development. But an equally important reason is the high cost of marketing. The U.S. Congress's Office of Technology Assessment (OTA) estimates that the industry spends roughly \$11 billion a year on promotion and marketing of drugs to physicians, compared with the \$10 billion that it reports spending on the development of new drugs.

One might ask why, if these new drugs are such major advances, must so much money be expended to promote them to physicians? One reason is that the performance of most new products differs only subtly from that of other drugs in the same class. These subtle differences may be of critical importance to individual patients who do not respond well to existing treatments, but marketing campaigns typically try to convince physicians to substitute the new for the old in all situations, not just a few special cases.

Of the \$11 billion spent on drug promotion, \$3 billion is spent on advertising and more than \$5 billion is spent for sales representatives, of whom fewer than 5 percent have any formal training in pharmacy or

pharmacology. There are more than 45,000 sales representatives, each costing the companies an estimated \$125,000 or more, calling on the approximately 550,000 U.S. physicians. OTA estimates that the industry's marketing efforts add an average of 22 percent to the cost of every prescription.

Drug companies apparently find this strategy profitable because the number of sales representatives employed in the industry has increased by 40 percent in the past 10 years. Some managers in the pharmaceutical industry have predicted that health care providers' efforts to cut costs—for instance, by putting price restrictions on prescriptions—will reduce the industry's reliance on sales representatives. However, this change is not yet apparent. Moreover, even if marketing strategies change, it is not likely that marketing budgets will be reduced, because firms perceive this investment as vital to maintaining sales. Marketing expenses will therefore continue to drive up the price of prescription drugs, and with them the cost of health care.

Bias in the scientific literature

The scientific literature—much of it reporting the results of research funded by the pharmaceutical industry—does not provide an effective balance to the marketing information provided by the companies themselves. Pharmaceutical companies primarily fund research that has the potential to establish or improve a drug's place in the market. This leads to a preponderance of reporting that is favorable to particular new drugs. Meanwhile, many valuable scientific studies are never conducted. For instance, careful analyses of comparative safety or studies exploring the mechanisms underlying adverse side effects are not performed unless specifically required by the Food and Drug Administration (FDA).

But the FDA has little power to require pharmaceutical companies to provide additional research. The agency can demand only that drug companies demonstrate that a new drug is effective and relatively safe. If problems appear prior to marketing, the FDA can request further studies to quantify the risk of adverse effects. However, during development, only a few thousand patients are likely to receive significant exposure to a new drug. Many serious problems appear only after the drug is approved and marketed more widely. At that point, the FDA

cannot require that any further research be performed. It can require only that the manufacturer warn physicians, usually by adding the information to a package insert. But the insert is rarely read by physicians, and most potentially serious consequences are buried in a long list of trivial side effects.

The FDA can ban a drug only if it poses an imminent health risk that outweighs all potential benefits. As a result, few drugs are ever removed from the market.

The FDA plays no active educational role and is even forbidden to comment on the relative merit of drugs or to otherwise direct the practice of medicine.

A second source of bias in the medical literature is the research investigator's lack of enthusiasm for publishing a trial that has a negative result. Physicians are not eager to publish negative trials because the results imply that they formulated an incorrect hypothesis. They are more eager to publish papers that will show that they helped to find new and effective treatments. In addition, the drug companies encourage the publication of trials that have favorable outcomes and aggressively promote their results. This further biases the literature read by physicians.

Most physicians believe that they obtain their information about drugs from the medical literature and scientific conferences, but numerous studies find that they obtain their information primarily from industry sales representatives and the *Physicians' Desk Reference*, a commercial compilation of information reviewed by the FDA but selected by pharmaceutical manufacturers. A study by Jerry Avorn of Harvard Medical School and his colleagues found that in instances when the medical literature and drug-promotion materials were at odds, between 33 percent and 49 percent of practicing physicians agreed with the drug companies' marketing message.

Misleading claims

A recent study published in the *Annals of Internal Medicine* set out to assess the quality of the information being provided by pharmaceutical companies. After analyzing more than 100 advertisements in med-

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ical journals, the authors concluded that 32 percent of the claims were misleading, 57 percent had little or no educational value, and 44 percent would have led to improper prescribing practices. A similar study published in the *New England Journal of Medicine* concluded that as many as 41 percent of the reports from industry-sponsored educational symposia published in the medical literature included misleading claims.

In 1991, the FDA stepped up its review of drug advertising and

the promotion of drugs through the medical literature in order to ensure the accuracy of the industry's claims. However, it has no effective means to monitor or counter the flow of information provided by sales representatives.

A variety of evidence suggests that pharmaceutical-industry promotion encourages undesirable prescribing practices. Physicians often believe that they are providing the very best for their patients if they prescribe the newest and most costly drugs available—even though these drugs are less tested. For instance, the calcium channel blocker was extensively prescribed before there were sufficient data to justify its broad use; indeed, it remains overused.

Additional problems occur in the way that physicians prescribe drugs. Avorn and several of his colleagues have found that physicians place inadequate emphasis on history-taking and resort to the use of drugs even when nonpharmacologic approaches might be more effective. Other researchers have found that physicians regularly fail to individualize the dosage of drugs. Elderly patients frequently receive dosages that are excessive because they are not scaled down for their lower body weight. The pharmaceutical industry goes to great lengths to promote a simple and easily remembered dosing regimen for its products, since physicians are more likely to remember how to use a one-dosage-fits-all drug.

The misuse of prescription drugs resulting from physicians' reliance on inadequate or misleading information can create medical problems that endanger patients. Estimates of the magnitude of health care

problems resulting from incorrect prescriptions vary according to the class of drug prescribed and the type of problem encountered. A dramatic example was the rise in mortality among heart-attack survivors resulting from the use of sodium channel blockers to treat asymptomatic arrhythmias. (See "The Heart of the Matter" at right.)

Failed efforts

Aware that a problem exists, regulatory agencies and state governments have taken steps to improve the prescribing practices of physicians. The FDA has established warning campaigns and educational programs, and state governments have tried to restrict reimbursements or pass legislation to limit physicians' choices. The results are not encouraging.

Data on the effectiveness of FDA warnings is scarce because underreporting prevents quantification of specific adverse drug reactions. In extreme cases, such as the incidence of Reye's syndrome following aspirin use by children, widely promoted warnings appear to have been effective. But FDA warnings about other potentially life-threatening interactions between drugs, such as those involving nonsedating antihistamines such as Seldane, have failed to stem the occurrence of preventable adverse events. Some drugs, such as procainamide, carry explicit warnings reminding physicians of the need to monitor patients carefully. Yet potentially fatal complications continue to arise in patients using this and other potentially toxic drugs. These examples confirm findings by Stephen Soumerai of Harvard Medical School and other researchers that regulatory warnings and even limitations on prescriptions (such as a no-refill rule) have insufficient impact on prescribing practices.

Soumerai has collaborated with Avorn on a number of studies identifying the factors that influence physicians' prescribing practices. He and his colleagues have also investigated the effectiveness of

The Heart of the Matter

The use of sodium channel blockers to treat arrhythmias in cardiac patients demonstrates how marketing efforts can contradict sound medical practice.

In the 1980s, drug companies alerted physicians to research indicating that when patients had asymptomatic irregularities in their heart rhythms, they were at increased risk for sudden death. The companies helped popularize the term "potentially malignant arrhythmias" for these asymptomatic skips in heartbeat and developed several new drugs (known as sodium channel blockers) that could correct them. Millions of dollars were spent to market these drugs and millions of patients were treated. Indeed, two published surveys found that physicians would prescribe these drugs for 80 percent to 90 percent of patients. Yet there was no scientific proof that correcting asymptomatic skips in heart rhythms altered survival rates at all.

In 1987, the National Institutes of Health (NIH) embarked on a \$55-million study, the Cardiac Arrhythmia Suppression Trial (CAST), one of whose purposes was to test this hypothesis in patients who had recently had a heart attack. The trial was halted because it clearly showed that the three sodium channel blockers being studied (encainide, flecainide, and morizicine) increased mortality—even though they had effectively corrected the arrhythmia. It has been estimated that several thousand patients died because they were treated with these drugs prior to the results of CAST.

state efforts to mandate changes in these practices. When a state Medicaid program limited the number of prescriptions that could be provided to each patient in an attempt to reduce costs, for instance, the number of prescriptions written fell by 30 percent. The prescriptions most commonly dropped were those for drugs deemed ineffective. However, there were also large declines in the number of prescriptions issued for essential drugs, such as insulin and medications for hypertension and heart failure. This unintended outcome surely outweighed any monetary savings. Indeed, the researchers found that during the time when restrictions were in effect, the rate at which elderly patients were admitted to nursing homes increased, thus increasing overall Medicaid costs.

In another state, legislative efforts to reduce costs by refusing to pay for a group of drugs of questionable value led to increases in the number of prescriptions for other drugs, canceling out any savings. Undesir-

Subsequently, the FDA and the NIH mounted a campaign to inform physicians of the harm caused by sodium channel blockers and of the fact that none of the drugs in their class had been proven effective in reducing mortality. Instead of stopping antiarrhythmic therapy, however, physicians responded to promotional campaigns by other companies and prescribed a similar drug, mexiletine.

This news was especially disturbing because an earlier, company-sponsored trial with mexiletine had been terminated prematurely because of a trend toward increased mortality in the drug-treated population. This study was generally discounted at the time, since the numbers involved were too small for the findings to be statistically significant. But in light of the findings of the later studies of sodium channel blockers, researchers were dismayed to see physicians simply convert patients from one ineffective and potentially fatal form of treatment to another that may pose similar risks.

CAST researchers also reported what other drugs were prescribed for the patients in the study. The standard therapy for these patients should have included the prescription of beta blockers, drugs that have been proven to reduce the risk of sudden death and reinfarction. Although almost every patient in the study was a candidate for beta-blocker therapy, cardiologists had prescribed these potentially life-saving drugs for only 33 percent of the patients. But 50 percent of the patients received prescriptions for calcium channel blockers, heavily marketed drugs that the medical literature indicates are ineffective and potentially lethal in some patients.

able as well as desirable drugs were substituted for the nonreimbursable medications. Similarly, the General Accounting Office (GAO) conducted a study of Canada's Patented Medicine Prices Review Board, which has the power to apply sanctions in cases where the price of a prescribed drug is excessive. The GAO concluded that the board did not slow the increase in drug spending. Other factors, such as the number of prescriptions written and the mix of new, costly products with older, cheaper drugs, offset any savings.

A recent example of how the pharmaceutical industry can circumvent efforts to restrict the rising cost of prescription drugs is Merck-Dupont's decision to stop producing certain medications in single-dose packages. Although it is more expensive to produce individually packaged medications, these were being sold at a lower price than those packaged in large volumes because they were usually sold to major clients,

such as hospitals, that can negotiate significant discounts. The company made its decision in order to circumvent the 1991 Medicaid Drug Rebate Law, which requires pharmaceutical companies to give Medicaid the best discounted price available to any client. By canceling the production of drugs packaged in single doses and sold at a very low price to hospitals, the company effectively increased costs to consumers and boosted profits without technically having raised its prices.

In contrast to the failure of the top-down approaches is the promise found in several small-scale, experimental efforts to educate physicians in the hope of influencing their prescribing practices. As long as these efforts have been sustained, they have generally proven effective.

In some cases, trained personnel worked with physicians on a one-to-one basis. Using computerized databases, researchers identified physicians with poor prescribing practices and offered them information about ways to improve

their performance. In each case, physician practices improved, but only for as long as personal contact was continued. Especially in light of the onslaught of new marketing information from the pharmaceutical companies, efforts are needed to maintain and update physicians' prescriptive skills.

Clinical pharmacologists at the Royal Melbourne Hospital in Australia took another tack. They demonstrated that an advertising campaign aimed at physicians and modeled on commercially successful techniques was able to correct inappropriate prescribing habits and reduce the cost of medical therapy. The hospital invested about \$10,000 in direct mail, pads, pencils, posters, and other items. Within months, the hospital had recouped the full amount through savings on unnecessary or ineffective prescriptions.

Having reviewed the alternatives, Soumerai and Avorn conclude that physician education and peer

pressure are the most effective means to provide a sustained improvement in physicians' prescribing practices. Other studies support this conclusion and suggest that the intervention must appeal to the physician's desire to provide the best care for patients—rather than solely to cut costs—in order to be effective. In addition, it is essential that the information given to physicians come from a qualified and unbiased source. Finally, it must emphasize and reinforce the basic principles of therapeutics. To limit the impact of high drug prices and poor prescribing practices on the cost—and quality—of health care, we must create a scientifically based research and education program that incorporates these essential components.

A potential solution

It is unrealistic to expect that pharmaceutical companies, which must remain profitable to survive, will ever be motivated to generate and distribute all of the information necessary to give physicians a balanced perspective on the drugs they manufacture. What our society needs is research that will allow those who prescribe drugs to make an informed and cost-effective choice of therapies. In addition, physicians and other health care providers must relearn the basic principles of therapeutics. This education must be provided by physician-educators in a structured and sustained program that can effectively modify prescribing practices.

The most logical source of research and education is the existing infrastructure of medical centers that employ physicians trained in clinical pharmacology. There are currently 11 university-based clinical pharmacology training programs sponsored by the National Institute of General Medical Sciences (NIGMS), a branch of the National Institutes of Health. Under Congressional mandate, four new training programs are being created with financial support and direction from the FDA. Although they are funded to train only clinical pharmacologists, all of these programs also conduct research and train local physicians in the principles of rational therapeutics. In addition, there are 20 clinical pharmacology training programs that do not now receive federal support. These 35 centers have the expertise to provide unbiased research and education for the nation's practicing physicians, but their research funding—most of which comes from the pharmaceutical industry for

narrowly focused studies—is limited, and they lack the capital to create the massive educational program needed to reach all the practicing physicians in the United States.

Congress should authorize the establishment of federally funded regional centers for education and research in therapeutics (CERTs). To guarantee their objectivity and maximize their effectiveness, the centers should be given adequate financial support to conduct their mission without reliance on support from the pharmaceutical industry. The sites for these centers should be chosen on the basis of peer review, and we can expect the 35 existing training programs in clinical pharmacology to be among the strongest candidates.

Each CERT would require a budget of roughly \$2.5 million to \$5 million annually. To fund 15 sites will cost no more than \$75 million annually—a small investment to balance the \$11 billion spent annually to market drugs to physicians. The best approach would be direct appropriation of funds for distribution by the FDA, which is familiar with the problem and has the expertise to oversee research and the education of clinical pharmacologists. Other options are to use FDA funds or include funding for CERTs in the federal appropriation for health care reform or in the appropriation for the Agency for Health Care Policy and Research. Surcharges on user fees paid by the pharmaceutical industry, physicians' licensing fees, or pharmaceutical advertisements could also be a source of funds. But this type of funding would have to be structured carefully to ensure that the CERTs are unencumbered by any perception of commercial influence.

Regardless of how they are funded, the CERTs should be administered by the FDA. This would prevent duplication of effort and ensure that the centers address areas of need as they evolve. FDA staff can serve as lecturers in CERT teaching programs; physician-scientists at the FDA can collaborate with the CERTs' research faculty. In addition to performing their primary mission of research and education, the CERTs will provide an important resource for monitoring drug safety and physician prescribing practices.

Research. Some of the neglected areas in which the CERTs could sponsor clinical and basic research include:

- Research on comparative forms of therapy. Specifically, is a new drug better or safer than the avail-

able alternatives? Under what circumstances should it be prescribed?

- Studies of the mechanisms by which a given drug produces side effects and of the patient characteristics that might help to predict adverse drug reactions. This information will help physicians tailor medication to a patient's needs, avoid adverse reactions, and perhaps eventually develop medications with fewer side effects.

- Development of new methods to test generic drugs. Existing tests use blood levels of the drugs to establish equivalency of different formulations. However, this standard does not accurately reflect the effectiveness of all drugs. Moreover, it is difficult to prove the efficacy of generic equivalents for complex medications, such as the estrogen supplement Premarin, which involve more than one potentially active ingredient. More effective and accurate tests will permit the development and evaluation of a wider range of generic drugs.

- Evaluation of new clinical applications for generic drugs. Pharmaceutical companies have little interest in exploring new applications for drugs whose patents have expired, since the profit margin is likely to be low. Similarly, CERTs could conduct research on new applications for orphan drugs—those with a limited market—which could help to reduce the cost of these medications.

- Dosage determination and safety evaluation for women, children, the elderly, and patients with special conditions, such as liver or kidney impairments. Pharmaceutical research often focuses only on narrowly defined patient populations, without exploring whether the results can be extrapolated to others. Additional information is needed to provide optimal treatment for women, children, and the elderly and to prevent overmedication and adverse effects in these populations.

- Pharmacoeconomic studies to assess the cost-effectiveness of various drugs within given populations. This information will help the pharmaceutical industry and health care insurers to develop guidelines for pricing and reimbursement.

*Congress
should support
regional programs
to provide
independent
research
and education
on drug quality
and performance.*

Based on their research, the CERTs could formulate and test consensus guidelines for specific forms of therapy, such as anticonvulsant therapy. Hospitals, professional groups, or government agencies often develop consensus guidelines for standard medical problems. However, these guidelines are usually based on a review of an inadequate scientific literature. The lack of data comparing different forms of treatment makes it difficult to determine the best standard practice: We know what works, but we don't know what works best. The CERTs can either test the guidelines themselves or

participate in the design of multicenter clinical trials to assess and refine guidelines for standard practice.

Education and training. The CERTs can play an important role in training physicians in clinical pharmacology and in improving the therapeutic skills of practicing clinicians. Right now, there is a severe shortage of physicians trained in clinical pharmacology. The 35 existing programs are not enough. Each of the 200 or so major teaching hospitals in the country should have from three to five clinical pharmacologists. Yet each year, only 25 to 30 doctors are trained in clinical pharmacology, and most of these go to work in the drug industry or the FDA. The CERTs could begin to close this gap by graduating 100 to 150 clinical pharmacologists a year.

Each CERT will conduct regional symposia and seminars for physicians, physician assistants, pharmacists, and nurses. Special courses will be conducted for members of local or state formulary committees, which are responsible for selecting the treatment options among which physicians may choose. These courses will provide education in the principles of therapeutics. In addition, each center shall staff and maintain a phone-in, e-mail, and/or fax service for consulting with local physicians and health care workers. It will also maintain a resource database of expert consultants for rare or uncommon therapeutic problems and will publish research results in the medical literature as well as issue periodic newsletters on topics of interest to practitioners.

Safety surveillance. The CERTs will assist the FDA in monitoring the safety issues arising from drug performance and physicians' practices. It can encourage physicians to participate in voluntary programs, such as the FDA's Medwatch, for reporting adverse drug reactions. CERTs' staffs can also lend their expertise in analyzing these reports to ensure that each incident indeed represents a drug reaction and not some other problem, and credits the proper drug. (The Medwatch program currently has no independent mechanism for assessing the accuracy of these reports.) The CERTs can also conduct pharmaco-epidemiologic research to identify rare but serious adverse reactions to new drugs.

Using databases such as that generated by Medicare's Drug Utilization Review program, CERTs' staffs could identify and educate physicians whose prescribing practices fall outside established norms. Although the Drug Utilization Review program should eventually allow Medicare officials to review the appropriateness of every prescription issued, it contains no educational component to improve physicians' therapeutic performance. To enhance these efforts, the CERTs can also establish and test indicators that suggest the presence of specific problems in prescription practices.

Better products, better prices

Although the CERTs can lower health care costs by helping providers choose the most appropriate treatments, it is unclear whether they will directly reduce the price of drugs. It is simply impossible to predict how the market will respond to changes in demand patterns based on physicians' access to more accurate information. Competition among manufacturers may increase in some cases and decrease in others. But in the best of all possible worlds, CERTs will discourage pharmaceutical companies from spending money on marketing appeals that are not supported by independent scientific research.

The CERTs will be of tremendous value to the pharmaceutical industry. They will provide a respected, unbiased source of post-marketing data, including cost-benefit analyses. They will point the way for the development of potentially profitable new drugs and will allow some drug manufacturers to build market share based on the real strengths of their products.

Last, the CERTs will provide a much-needed increase in the number of clinical pharmacologists trained and available to join the industry as employees.

Most important, the creation of the CERTs will forestall efforts to legislate restrictive changes on the part of either physicians or the pharmaceutical industry. In recent years, a number of bills have been proposed to create restrictive national and state formularies, as well as to limit drug advertising and promotion. Unlike these proposals, the CERTs' educational and research programs would maintain (and strengthen) the incentive for the pharmaceutical industry to develop new forms of therapy. Companies would be less likely to invest in marginal improvements and more likely to concentrate on drugs that have obvious advantages. In short, the CERTs would complement the market mechanisms that have laid the foundation for the pharmaceutical industry's financial and medical success.

Research and education are essential to improving the quality and cost-effectiveness of drug therapy. With access to full and balanced information, generated by the CERTs, physicians will be able to provide optimal drug therapy at a reasonable cost. In a free-market society, government has the responsibility to provide the checks and balances to ensure that physicians have all the information that they need to provide optimal cost-effective care.

Recommended reading

- J. Avorn, M. Chen, and R. Hartley, "Scientific versus Commercial Sources of Influence on the Prescribing Behavior of Physicians," *American Journal of Medicine*, 73 (1982): 4-8.
- CAST investigators, "Preliminary Report: Effect of Encainide and Flecainide on Mortality in a Randomized Trial of Arrhythmia Suppression After Myocardial Infarction," *New England Journal of Medicine*, 321 (1989): 406-412.
- W. R. Ray, M. R. Griffin, and J. Avorn, "Evaluating Drugs After Their Approval for Clinical Use," *New England Journal of Medicine*, 329 (1994): 2029-2032.
- S. B. Soumerai, et al. "Effect of Government and Commercial Warnings on Reducing Prescription Misuse: The Case of Propoxythene," *American Journal of Public Health* 77 (1987): 1518-1523.

Mr. COYNE. Thank you very much for your testimony. The next witness will be Dr. Lione.

STATEMENT OF JOHN LIONE, M.D., MEMBER, BOARD OF DIRECTORS, AMERICAN ASSOCIATION OF RETIRED PERSONS

Dr. LIONE. Good morning, Mr. Chairman and members of the subcommittee. My name is John Lione. I am from Austin, Tex. I am a member of AARP's board of directors and a retired physician.

AARP is pleased to discuss mismedication and its impact on older Americans. Older Americans comprise 13 percent of our Nation's population, but consume 34 percent of all prescription drugs, and they are disproportionately affected by mismedication.

Given this, AARP is deeply concerned about the adverse reactions that can result from mismedication, including drug-induced illnesses, hospitalization and even death. We believe that mismedication often can be avoided if proper precautions are taken by providers and patients and appropriate information and education are provided to health professionals and patients by the government, drug manufacturers, and the medical community.

Today I will address the extent of mismedication and its consequences, the factors underlying mismedication, and recommendations for reducing the incidence of mismedication.

The consequences of mismedication have been well documented, and studies have found mismedication to be a serious problem in all settings, including nursing homes, hospitals, and community settings. In 1987, at least 200,000 older Americans were hospitalized for an adverse drug reaction or experienced one while hospitalized. Moreover, persons over age 60 accounted for 51 percent of the ADR-related deaths. And a recent RAND Corp. review estimated that 40 percent of nursing home residents, age 65 and over, received inappropriate medication orders.

Clearly mismedication is a serious problem amongst older adults; both personally in terms of loss of health and even life, and financially in terms of millions of dollars spent on avoidable health care services.

While ADRs that result in hospitalization are quite serious, less serious ADRs can still cause significant problems. A recent study published in the *Journal of the American Medical Association* reports that only a small percentage of ADRs result in hospitalization. "Subtle but important side-effects such as sedation or cognitive impairment resulting in falls may easily go unrecognized."

The study found a disturbingly high level of potentially inappropriate prescribing for older people living in the community with almost one-quarter unnecessarily exposed to potentially hazardous prescribing.

For older Americans, mismedication can result from any one of a number of factors. First, the physiological effects, changes that accompany the aging process, make older persons more susceptible to ADRs caused by drug toxicity. Yet many of the drugs used to treat conditions common among the elderly were not clinically tested on older persons, and many drugs do not have specified dosage schedules that are appropriate for the elderly patients.

A second factor is the failure of medical education to include sufficient course work in both pharmacology and geriatrics. Com-

pounding this problem is a lack of continued education in these areas.

The lack of counseling by health professionals is a third factor. Counseling by doctors and pharmacists is especially important for elderly patients who may be taking several medications prescribed by multiple physicians. Yet in 1989, an AARP survey indicated over one-third of the patients are not being counseled by their doctors on even the most basic aspects of their different drug therapies.

A fourth factor is the underreporting of medication errors and ADRs. Reports from health professionals of errors, adverse events, and product quality problems are essential to ensure the safety of drugs, biologicals, and medical devices. Although voluntary reporting programs exist, many health professionals have no incentive and do not think it is important to report the adverse events.

AARP believes that the collection and study of these data are critical to help the health care community to detect and prevent adverse events.

To help reduce the incidence of mismedication, the Association has the following recommendations:

First, we recommend improving elderly specific information on drugs, particularly information about drug risks and the effects of drug interactions. Drug labels should include information for physicians and pharmacists about drug use by the elderly, and clinical testing of new drugs should require more reasonable representation by older patients.

Also information about drug use and effects should be made available to patients through patient package inserts that provide drug-specific information in clear language. Pharmacists should be required to include an insert with each new prescription.

Second, AARP believes that much more vigorous physician education in pharmacology and geriatrics is needed to improve the safety of prescribing. Also physicians and pharmacists must be encouraged to make the effort to properly and thoroughly counsel their patients regarding the appropriate use of medications.

Third, physicians and pharmacists should be encouraged to review all the drugs that a patient is taking. Online computerized prospective review of prescriptions at the point of purchase can immediately identify potential problems for a patient. Such systems should be used by all pharmacists on a routine basis.

And fourth, since many health professionals do not report adverse events, we believe it is reasonable to require such reporting. Such information can help minimize unnecessary ADRs and greatly enhance the quality of patient care, particularly amongst older Americans.

At a minimum, AARP believes the Congress should investigate why voluntary reporting programs are underutilized.

AARP appreciates the opportunity to testify today. We firmly believe that reducing the incidence of mismedication will both increase the quality of care provided to all Americans and reduce the costs associated with avoidable ADRs. We look forward to working with the subcommittee and others in Congress to improve the quality of health care provided to all Americans. Thank you.

[The prepared statement follows:]

**TESTIMONY OF JOHN LIONE, M.D.
AMERICAN ASSOCIATION OF RETIRED PERSONS**

Good morning Mr. Chairman and members of the Subcommittee. My name is John Lione from Austin, Texas. I am a member of AARP's Board of Directors and a retired physician. AARP is pleased to have the opportunity to discuss mismedication, including medication errors and inappropriate prescribing, and its impact on older Americans. We believe that mismedication is an issue that must be addressed to improve the quality of health care and reduce unnecessary medical costs and avoidable drug-induced illnesses.

AARP has always maintained a keen interest in prescription drug issues. Older Americans, who comprise 13 percent of our nation's population but consume 34 percent of all prescription drugs, are disproportionately affected by mismedication. Given this, the Association is deeply concerned about the adverse reactions that can result from mismedication, including drug-induced illnesses, hospitalization, and even death. We believe that mismedication often can be avoided if proper precautions are taken by providers and patients, and appropriate information and education are provided to health professionals and patients by the government, drug manufacturers, and the medical community.

My testimony today will address:

- the extent of mismedication and its consequences;
- factors underlying mismedication; and
- recommendations for reducing the incidence of mismedication.

The Extent of Mismedication and Its Consequences

Some of the consequences of mismedication have been well-documented. For example, a 1992 review article in Drugs & Aging found that between three and eleven percent of hospital admissions could be attributed to adverse drug reactions (ADRs) caused by mismedication. Unfortunately, many of these ADRs can be quite serious. A study published in the Pittsburgh-Post Gazette of 250 hospital pharmacists across the country estimated that there were 16,000 medication errors in their institutions in 1992 and 106 of them caused patient deaths.

Older Americans experience more mismedication than do other age groups, and they are disproportionately affected by this problem. Studies have found mismedication to be a serious problem in all settings, including nursing homes, hospitals, and community settings. A recent RAND Corporation review estimated that 40 percent of nursing home residents age 65 and over received inappropriate medication orders. This high incidence of mismedication has extraordinary costs -- both personal in terms of loss of health and even life, and financial in terms of millions of dollars spent on avoidable health care services. In 1987, at least 200,000 older adults were hospitalized for ADRs or experienced an ADR while hospitalized. Moreover, persons over age 60 accounted for 51 percent of ADR-related deaths. Clearly, mismedication is a serious problem among older adults.

While ADRs that result in hospitalization are quite serious, less serious ADRs can still cause significant problems. A July, 1994 study published in The Journal of the American Medical Association reports that although only a small

portion of ADRs result in hospitalization, "subtle but important side effects such as sedation or cognitive impairment resulting in falls may easily go unrecognized." The study found a disturbingly high level of potentially inappropriate prescribing for older people living in the community, with almost one-quarter unnecessarily exposed to potentially hazardous prescribing.

Factors Underlying Mismedication

For older Americans, mismedication can result from any one of a number of factors. First, the physiological changes that accompany the aging process — such as a decrease in the efficiency of liver and kidney functions — make older persons much more susceptible to ADRs caused by drug toxicity. Yet, many of the drugs used to treat conditions common among the elderly were not clinically tested on older persons. As a result, many drugs do not have specified dosage schedules that are appropriate for elderly patients, and the practitioner is only advised to "use with caution in elderly or debilitated patients." While such advice may prompt physicians to monitor elderly patients more closely, it is not an adequate substitute for clinically-tested safe dosage schedules.

A second factor underlying the problem of mismedication is poor prescribing practices. Such practices reflect, in part, the failure of medical education to include sufficient course work in both pharmacology and geriatrics. A 1985 survey of U.S. medical schools found that only 14 percent of them had required courses in core skills and principles of therapeutic decision-making and clinical pharmacology. Of the remainder, 87 percent taught only a few hours of clinical pharmacology, and most of the teaching occurred in the early years of medical training. Compounding this problem is the lack of continuing education in pharmacology and geriatrics.

A lack of counseling by health professionals is a third factor contributing to mismedication. Counseling by doctors and pharmacists is especially important for elderly patients, yet a 1989 AARP survey indicated that over one-third of patients are not being counseled by their doctors on even the most basic aspects of their drug therapies. A medication label which states, "take as directed," is not sufficient instruction for an elderly person who may be taking several medications prescribed by multiple physicians. In addition, appropriate counseling should include a review of all medications that the patient is taking to prevent dangerous interactions and reduce the incidence of mismedication, overmedication, and other inappropriate prescribing practices.

A fourth factor is the under-reporting of medication errors and ADRs. Reports from health professionals of errors, adverse events, and product quality problems are essential to ensure the safety of drugs, biologicals, and medical devices. The Food and Drug Administration (FDA) has a voluntary program called "MEDWatch" which encourages such reporting, and the U.S. Pharmacopeia coordinates another voluntary reporting program.

Unfortunately, many health professionals have no incentive and do not think it is important to report adverse events. According to a 1987 study published in the Rhode Island Medical Journal, only about one percent of serious events are reported to the FDA. AARP believes that the collection and study of these data

are critical to help the health care community detect and prevent adverse events. This information can then be disseminated to heighten the understanding and awareness of drug-induced illness among all professionals involved with medications.

Recommendations for Reducing the Incidence of Mismedication

To help reduce the incidence of mismedication, the Association has the following recommendations for the subcommittee's consideration:

1) Improve Elderly-Specific Information on Drugs.

The fact that health care providers and consumers are not given enough information about the drugs being prescribed is a major contributor to the problem of mismedication. Elderly-specific information about drug risks and the effects of drug interactions are particularly important. FDA's 1989 publication of "Guidelines for the Study of Drugs Likely to be Used by the Elderly" was a significant step toward encouraging manufacturers to routinely and thoroughly evaluate the effects of drugs in older Americans.

AARP strongly supports requiring that prescription drug labels include information for physicians and pharmacists about drug use by, and effects on, the elderly. In addition, we believe that the clinical testing of new drugs or new uses of currently marketed drugs should require more reasonable representation by the elderly, particularly for drugs intended for use primarily among older patients.

The Association also recommends that the FDA require that information about drug use and effects be made available to patients through patient package inserts (PPIs) -- pamphlets that accompany prescription products and provide drug-specific information in clear and understandable language in large, legible print. Pharmacists should be required to include a PPI with each new prescription.

2) Improve the Education of Physicians on Drug Use in Older Patients and Encourage More Patient Counseling.

AARP believes that much more vigorous physician education in pharmacology and geriatrics (both initially in medical school and through continuing medical education) is needed to improve the safety of prescribing and reduce the incidence of unnecessary ADRs. In addition, both physicians and pharmacists need to make the effort to properly and thoroughly counsel their patients regarding the appropriate use of medications. AARP believes that patient counseling is the professional responsibility of all prescribers and should be strongly encouraged by the medical profession.

3) Encourage Greater Use of Drug Utilization Review.

To reduce the incidence of dangerous drug interactions, mismedication, overmedication, and other inappropriate prescribing practices, physicians and pharmacists should be encouraged to review all the drugs a patient is taking.

On-line computerized prospective review of prescriptions at the point of purchase can immediately identify potential problems for the patient. Such systems should be used by all pharmacists on a routine basis.

4) Require Reporting of Serious Adverse Events.

AARP is encouraged by the voluntary reporting programs administered by the FDA and the U.S. Pharmacopeia. However, we are concerned that these voluntary programs are greatly underutilized. Since many health professionals do not report adverse events, we believe it is reasonable to require such reporting. At a minimum, AARP believes the Congress should investigate why these voluntary programs are underutilized. For example, are health care providers reluctant to report such incidents due to potential liability problems?

AARP supports H.R. 3632, "The Safe Medications Act," as introduced by Representative Coyne and cosponsored by Chairman Stark, which would require health providers to notify the FDA of deaths caused by medication errors. We recommend that the legislation be expanded to require reporting of all serious adverse events caused by mismedication, including those that result in: 1) death; 2) a life-threatening condition; 3) initial or prolonged hospitalization; 4) disability or congenital anomaly; or 5) when intervention was required to prevent permanent impairment or damage.

AARP recognizes the value of establishing a mandatory reporting system that will help medical personnel anonymously share their experience with adverse events caused by mismedication with their peers. The FDA should use this information to educate the medical community and heighten physician awareness of drug-induced illnesses so prescribers can better recognize and avoid situations that lead to mismedication. Such information can help minimize unnecessary ADRs and greatly enhance the quality of patient care, particularly among older Americans.

AARP, however, views mandatory reporting as an initial step in a broader policy that should include establishing an entity responsible for: 1) analyzing this data for its implications on prescribing, pharmacy practice, and nursing care; 2) making public policy recommendations; and 3) enforcing proper reporting.

Conclusion

AARP appreciates the opportunity to testify before this Subcommittee on this important issue for older Americans. We firmly believe that reducing the incidence of mismedication will both increase the quality of care provided to older Americans and reduce the costs associated with avoidable ADRs. We look forward to working with this Subcommittee and others in Congress to improve the quality of health care provided to all Americans.

Chairman STARK. Thank you, Dr. Lione.
Mr. Ellis.

**STATEMENT OF WILLIAM M. ELLIS, R.PH., M.S., EXECUTIVE
DIRECTOR, PENNSYLVANIA SOCIETY OF HOSPITAL
PHARMACISTS ON BEHALF OF THE AMERICAN SOCIETY OF
HOSPITAL PHARMACISTS**

Mr. ELLIS. Good morning, Mr. Chairman and members of the Subcommittee on Health.

My name is William Ellis. I am a licensed pharmacist and have been employed since 1986 as the executive director of the Pennsylvania Society of Hospital Pharmacists. I am pleased to present testimony before you this morning on behalf of the American Society of Hospital Pharmacists, ASHP.

ASHP is a 30,000-member national professional association representing pharmacists in health care systems including hospitals, health maintenance organizations, long-term care facilities, and home care agencies. ASHP's membership spans all 50 States, including the District of Columbia. The society has extensive publishing and educational programs designed to help members improve the delivery of pharmaceutical care and is a national accrediting organization for pharmacy residency and pharmacy technician training programs.

Medications are an important part of health care in the United States. In fact, medications are among the most effective tools that health professionals have to fight disease and to improve the quality of people's lives.

However, potent medications, when used improperly, confused with other agents, administered for the wrong indication or given to the wrong patient can cause injury or death. With those consequences, the responsibility to assure the optimal patient outcome is one that members of our organization take very seriously. My experience has been that the overwhelming majority of pharmacists strive for absolute perfection in their work. The complex nature of drug therapy demands no less.

However, one barrier to perfection is the human condition. Human error is part of society. If we acknowledge that human error can and will occur, then our efforts should be to create systems and strategies to minimize human error and reduce the adverse consequences.

The problems and sources of medication errors are multidisciplinary and multifactorial. Errors from lack of knowledge, substandard performance, mental lapses, defects or failures in systems occur.

Medication errors may be committed by both experienced and inexperienced staff, including pharmacists, physicians, nurses, pharmacy technicians, students, clerical staff, administrators, pharmaceutical manufacturers, patients, and their caregivers.

The incidence of medication errors is indeterminate. Valid comparisons of different studies on medication errors is extremely difficult, because of the difference in variables, measurements, populations, and methods.

In the February 1993 issue of the American Journal of Hospital Pharmacy, the society published a report entitled "ASHP Guide-

lines on Preventing Medication Errors in Hospitals." We are pleased to make copies of this report available to you this morning.

This document represents guidelines for all health care practitioners to use in developing comprehensive systems approaches to medication errors prevention. While the guideline is comprehensive in offering a variety of recommendations for preventing medication errors including those specifically aimed at prescribers, pharmacists, nurses, and patients, I would like to briefly comment on the organizational aspects which illustrate the necessity to approach this issue from a multidisciplinary, organizational perspective, including the development of adequate policies and procedures.

For example, care must be given to hiring and assigning personnel involved with medications. Policies should be developed that ensure adequate training, supervision, and evaluation.

Sufficient personnel must be available to perform tasks adequately, and a suitable work environment should exist for the preparation of drug products.

All systems should provide for a review and verification of the prescriber's order before the drug product is dispensed or administered. This is an ideal role for the pharmacist to play and is actively participated in and accomplished by our membership.

It is recommended that there be computerized pharmacy systems in place that enable automatic checking of doses, duplicate therapies, allergies, drug interactions, and other aspects of drug use.

The pharmacy department, in conjunction with nursing, risk management, and the medical staff, should conduct ongoing educational programs to discuss medication errors, their causes, and methods to prevent their occurrence.

ASHP is also pleased to announce that a multidisciplinary consensus conference on understanding and preventing drug misadventures will be held October 21, 22, and 23 of this year. The society is pleased to extend an invitation to members of this committee and their staff to attend that conference.

In cooperation with the American Medical Association, the American Nurses Association, the ASHP will bring together representatives from these disciplines to focus on understanding the dimensions of the problem and exploring methods of prevention.

Objectives of the conference include an increased awareness of opinion leaders among practicing physicians, pharmacists, and nurses about the extent and seriousness of drug misadventures in health systems; an outline of model strategies that can be used in health care practice settings to increase awareness of the problem of drug misadventures; an outline of model interdisciplinary strategies that can be applied in health care practice settings to monitor, prevent, and manage drug misadventures.

I think it is important, based on some comments that we heard this morning, to define terms that were used interchangeably.

"Drug misadventure," for example, refers to the broadest-based definition, which includes medication errors, includes adverse reactions, anything where the optimum outcome is not reached, and you heard Dr. Perper comment on that very broad term.

"Medication errors," though, really need to be differentiated from adverse reactions. Medication errors are preventable and can occur

from any number of things that we talked about today. But adverse reactions are oftentimes predictable, and they are different from medication errors, and they can involve things such as nausea and vomiting and other adverse effects. And so they are really different, and the strategies to address those can be different. There may be some areas of overlap, but then there are also areas where that is very different. So I think it is important for this subcommittee to keep that in mind.

There is value in distributing information about how misadventures occur as a means of avoiding future tragedies. The U.S. Pharmacopeial Convention, together with the Institute for Safe Medication Practices, operates a voluntary reporting system for medication errors, including death under the name of the USP-ISMP medication error reporting program.

Under this program, these organizations act as a clearinghouse for medication error reports from a wide variety of health care settings and professionals, disseminating findings as appropriate to manufacturers and the Food and Drug Administration.

The FDA scrutinizes this data, though its primary focus is on the evaluation of information on adverse reactions it receives through its MedWatch program. The USP-ISMP medication error reporting program has begun to assemble an impressive track record in identifying and resolving medication error problems.

ASHP supports the efforts of the USP and ISMP in collecting and acting upon medication error reports, and ASHP is also a MedWatch partner and maintains regular dialog with the Food and Drug Administration. Cooperation between these groups is very effective, as evidenced by the recent FDA safety alert about free-flow infusion devices, which was published in March 1994.

Both the medication error reporting program and the MedWatch program have gained wide acceptance among participants, because they gather appropriate information, process and release it quickly to the health care community, thus serving as an effective and confidential deterrent to future medication errors.

ASHP believes voluntary reporting systems historically invite the highest level of compliance from health care professionals and offer the greatest likelihood of protecting the public. The FDA has also stated their support of voluntary reporting in the Federal Register.

Furthermore, ASHP is committed to working with the aforementioned programs, and we would recommend that resources be directed to existing programs rather than the creation of programs that duplicate current initiatives. Forums such as the drug misadventure conference heighten the awareness of these issues and strengthen involvement in reporting programs.

It is important to point out that the cost of many of these initiatives are supported through private funding and do not use public funds raised through tax revenues.

There is no singular solution to eliminating medication errors. The answer lies, in some instances, with government agencies such as the FDA. Other answers are rooted in the development of practice standards and practitioner efforts such as those developed by the ASHP. Still other solutions can be found when pharmaceutical manufacturers design packaging and labeling to reduce the likelihood of error. Programs such as the USP-ISMP program, the

strong relationship between FDA and ASHP and other professional organizations provide an ideal foundation to continue the fight against medication errors.

In conclusion, ASH supports your interest in monitoring and reducing the incidence of medication errors, and we would welcome the opportunity to further discuss with the subcommittee specific suggestions for attaining this goal.

Specifically, assistance is needed in distributing information to health care professionals concerning error-reduction strategies. In addition, assistance in publicizing the current data collection programs would be extremely helpful.

Finally, the public needs to know that efforts are underway to reduce medication errors. Changes have been made to our health care delivery system that have virtually eliminated certain fatal errors.

The public should be pleased to know that this subcommittee is studying this issue. We hope that you find the efforts underway a significant step in addressing the problems associated with medication errors.

Mr. Chairman, on behalf of the American Society of Hospital Pharmacists, I thank you for the opportunity to present to you this morning.

[The prepared statement and attachment follow:]

**TESTIMONY OF WILLIAM M. ELLIS
AMERICAN SOCIETY OF HOSPITAL PHARMACISTS**

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Testimony of
The American Society of Hospital Pharmacists (ASHP)
before
The Committee on Ways and Means
Subcommittee on Health
Presented by
William M. Ellis, R.Ph., MS, Executive Director,
Pennsylvania Society of Hospital Pharmacists (PSHP)
September 20, 1994

Good morning Mr. Chairman and members of the Subcommittee on Health. My name is William Ellis. I am a licensed pharmacist and have been employed since 1986 as the Executive Director of the Pennsylvania Society of Hospital Pharmacists (PSHP). I am pleased to present testimony before you this morning on behalf of the American Society of Hospital Pharmacists (ASHP). ASHP is the 30,000-member national professional association representing pharmacist in health care systems, including hospitals, health maintenance organizations (HMOs), long-term-care facilities, and home care agencies. ASHP's membership spans all fifty states and the District of Columbia. The Society has extensive publishing and educational programs designed to help members improve their delivery of pharmaceutical care, and it is a national accrediting organization for pharmacy residency and pharmacy technician training programs.

Medications are an important part of health care in the United States. In fact, medications are among the most effective tools that health professionals have to fight disease and improve the quality of people's lives. However, potent medications, when used improperly, confused with other agents, administered for the wrong indication or given to the wrong patient, can cause injury of death.

With those consequences, the responsibility to assure the optimal patient outcome is one that members of our organization take very seriously. My experience has been that the overwhelming majority of pharmacists strive for absolute perfection in their work; the complex nature of drug therapy demands no less.

However, one barrier to perfection is the human condition. Human error is part of society. If we acknowledge that human error can and will occur, then our efforts should be to create systems and strategies to minimize human error and reduce adverse consequences.

"The problems and sources of medication errors are multidisciplinary and multifactorial. Errors occur from lack of knowledge, substandard performance and mental lapses, or defects or failures in systems. Medication errors may be committed by both experienced and inexperienced staff, including pharmacists, physicians, nurses, pharmacy technicians, students, clerical staff, administrators, pharmaceutical manufacturers, patients and their caregivers, and others. The incidence of medication errors is indeterminate; valid comparison of different studies on medication errors is extremely difficult because of the difference in variables, measurements, populations, and methods." (1)

In the February, 1993, issue of the *American Journal of Hospital Pharmacy (AJHP)*, the Society published a report entitled, *ASHP guidelines on preventing medication errors in hospitals*. We are pleased to make copies of this report available to you this morning. This document

represents guidelines for all health care practitioners to use in developing a comprehensive systems approach to medication error prevention. While the guideline is very comprehensive in offering a variety of recommendations for preventing medication errors, including those specifically aimed at prescribers, pharmacists, nurses, and patients, I would like to comment briefly on the organizational aspects -- which illustrate the necessity to approach this issue from a multidisciplinary, organizational perspective, including the development of adequate policies and procedures. For example:

- Care must be given to hiring and assigning personnel involved in medications. Policies should be developed that ensure adequate training, supervision and evaluation.
- Sufficient personnel must be available to perform tasks adequately.
- Suitable work environments should exist for the preparation of drug products.
- All health care systems should provide for review and verification of the prescriber's order before a drug product is dispensed or administered.
- It is recommended that there be computerized pharmacy systems in place that enable automated checking of doses, duplicate therapies, allergies, drug interactions, and other aspects of use.
- The pharmacy department, in conjunction with nursing, risk management, and the medical staff, should conduct ongoing educational programs to discuss medication errors, their causes, and methods to prevent their occurrence.

ASHP is also pleased to announce that a multidisciplinary consensus conference on understanding and preventing drug misadventures which will be held on October 21-23 of this year. In cooperation with the American Medical Association and the American Nurses Association, ASHP will bring together representatives of medicine, pharmacy and nursing to focus on understanding the dimensions of the problem and exploring methods of prevention.

Objectives of the conference include: (1) increase the awareness of opinion leaders among practicing physicians, pharmacists, and nurses about the extent and seriousness of drug misadventures in health systems; (2) outline model strategies that can be used in health care practice settings to increase awareness of the problem of drug misadventures; (3) outline model interdisciplinary strategies that can be applied in health care practice settings to monitor, prevent, and manage drug misadventures; and (4) identify steps that can be taken by health care professional societies and others, including third-party payers, regulatory agencies, and the pharmaceutical industry, to foster implementation of the practice-level strategies identified at the conference.

In addition, ASHP has made available two videotapes that provide strategies to reduce the potential for error. The Society also develops and distributes practice standards that are written to uphold the highest standards in patient safety. The *ASHP guideline on preventing medication errors in hospitals* is one example of such standards.

There is value in distributing information about how misadventures occur, as a means of avoiding future tragedies. The United States Pharmacopeial Convention (USP), together with the Institute for Safe Medication Practices (ISMP), operate a voluntary reporting system for medication errors, including deaths, under the name of the USP-ISMP Medication Errors Reporting Program. Under this program, these organizations act as a clearinghouse for medication error reports from a wide variety of health care settings and professionals, disseminating findings as appropriate to manufacturers and the Food and Drug Administration. The FDA scrutinizes these data, though its primary focus is on the evaluation of information on adverse reactions it receives through its MedWatch program. The USP-ISMP Medication Errors Reporting Program has begun to assemble an impressive record in identifying and resolving medication error problems.

ASHP supports the efforts of the USP and ISMP in collecting and acting upon medication error reports. ASHP is also a MedWatch partner and maintains a regular dialogue with the FDA. The cooperation between these groups is very effective, as evidenced by the recent FDA safety alert about free flow infusion devices released in March, 1994.

Both the Medication Error Reporting Program and the MedWatch program have gained wide acceptance among participants because they gather appropriate information and process and release it quickly to the health care community, thus serving as an effective and confidential deterrent to future medication errors. ASHP believes that voluntary reporting systems historically invite the highest level of compliance from health care professionals and offer the greatest likelihood of protecting the public.

Furthermore, ASHP is committed to continuing to work with the aforementioned programs. We would recommend that resources be directed to existing programs rather than the creation of programs that duplicate current initiatives. Forums such as the drug misadventures conference heighten awareness of these issues and strengthen involvement in reporting programs. It is also important to point out that the costs of many of these initiatives are supported through private funding and do not use public funds raised through tax revenues.

There is no singular solution to eliminating medication errors. The answer lies in some instances with government agencies such as the FDA; other answers are rooted in the development of practice standards and practitioner education efforts such as those developed by ASHP; still other solutions can be found when pharmaceutical manufacturers design packaging and labeling to reduce the likelihood of error. Programs such as the USP-ISMP Medication Errors Reporting Program and the strong relationship between the FDA, ASHP and other professional organizations provide an ideal foundation to continue to fight against medication errors.

In conclusion, ASHP supports your interest in monitoring and reducing the incidence of medication errors. We would welcome the opportunity to further discuss with the Subcommittee specific suggestions for attaining this goal. Specifically, assistance is needed in distributing information to health care professionals concerning error reduction strategies. In addition, assistance in publicizing the current data collection programs would be extremely helpful. Finally, the public needs to know that efforts are underway to reduce medication errors. Changes have been made to our health care delivery system that have virtually eliminated certain fatal errors. The public should be pleased to know that this Subcommittee is studying this issue. We hope you find the efforts currently underway a significant step in addressing the problems associated with medication errors. Mr. Chairman, on behalf of the American Society of Hospital Pharmacists, I thank you for the opportunity to address the Subcommittee this morning.

References:

- I American Society of Hospital Pharmacists. ASHP guidelines on preventing medication errors in hospitals. *Am J Hosp Pharm.* 1993; 50:305-314.

ASHP REPORT

ASHP guidelines on preventing medication errors in hospitals

Am J Hosp Pharm. 1993; 50:305-14

The goal of drug therapy is the achievement of defined therapeutic outcomes that improve a patient's quality of life while minimizing patient risk.¹ There are inherent risks, both known and unknown, associated with the therapeutic use of drugs (prescription and nonprescription) and drug administration devices. The incidents or hazards that result from such risk have been defined as drug misadventuring, which includes both adverse drug reactions and medication errors.² This document addresses medication errors—episodes in drug misadventuring that should be preventable through effective systems controls involving pharmacists, physicians and other prescribers, nurses, risk management personnel, legal counsel, administrators, patients, and others in the organizational setting, as well as regulatory agencies and the pharmaceutical industry.

This document suggests medication-error prevention approaches that should be considered in the development of organizational systems and discusses methods of managing medication errors once they have occurred. These guidelines are primarily intended to apply to the inpatient hospital setting because of the special collaborative processes established in the setting (e.g., formulary system, pharmacy and therapeutics [P&T] committee, opportunity for increased interaction among health care providers).

Recommendations for practice settings other than hospitals are beyond the scope of this document, although many of the ideas and principles may be applicable.

Medication errors compromise patient confidence in the health care system and increase health care costs. The problems and sources of medication errors are multidisciplinary and multifactorial. Errors occur from lack of knowledge, substandard performance and mental lapses, or defects or failures in systems.^{3,4} Medication

errors may be committed by both experienced and inexperienced staff, including pharmacists, physicians, nurses, supportive personnel (e.g., pharmacy technicians), students, clerical staff (e.g., ward clerks), administrators, pharmaceutical manufacturers, patients and their caregivers, and others. The incidence of medication errors is indeterminate; valid comparisons of different studies on medication errors is extremely difficult because of differences in variables, measurements, populations, and methods.²

See related commentary on page 315

Many medication errors are probably undetected. The outcome(s) or clinical significance of many medication errors may be minimal, with few or no consequences that adversely affect a patient. Tragically, however, some medication errors result in serious patient morbidity or mortality.¹ Thus, medication errors must not be taken lightly, and effective systems for ordering, dispensing, and administering medications should be established with safeguards to prevent the occurrence of errors. These systems should involve adequately trained and supervised personnel, adequate communications, reasonable workloads, effective drug-handling systems, multiple procedural and final-product checks by separate individuals, quality management, and adequate facilities, equipment, and supplies.

The pharmacist's mission is to help ensure that patients make the best use of medications.⁵ This applies to all drugs used by inpatients or ambulatory patients, including oral or injectable products, radiopharmaceuticals, radiopaque contrast media, anesthetic gases, blood-fraction drugs, dialysis fluids, respiratory therapy agents, investigational drugs, drug samples, drugs brought into the hospital setting by patients, and other

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chemical or biological substances administered to patients to evoke a pharmacological response.⁶ Through a systems-oriented approach, the pharmacist should lead collaborative, multidisciplinary efforts to prevent, detect, and resolve drug-related problems that can result in patient harm.¹ An understanding of the risk factors associated with medication errors should enable improved monitoring of patients and medications associated with increased risk for serious errors and should enable the development of organizational systems designed to minimize risk.⁷ The pharmacist should participate in appropriate organizational committees and work with physicians, nurses, administrators, and others to examine and improve systems to ensure that medication processes are safe.

Types of medication errors

Medication errors include prescribing errors, dis-

persing errors, medication administration errors, and patient compliance errors. Specific types of medication errors are categorized in Table 1, based on a compilation of the literature.^{1,7-18}

A potential error is a mistake in prescribing, dispensing, or planned medication administration that is detected and corrected through intervention (by another health care provider or patient) before actual medication administration. Potential errors should be reviewed and tabulated as separate events from errors of occurrence (errors that actually reach patients) in order to identify opportunities to correct problems in the medication-use system even before they occur. Detection of potential errors should be a component of the hospital's routine quality improvement process. Documentation of instances in which an individual has prevented the occurrence of a medication error will help identify system weaknesses and will reinforce the importance of

Table 1.
Types of Medication Errors^{1,7-18a}

Type	Definition
Prescribing error	Incorrect drug selection (based on indications, contraindications, known allergies, existing drug therapy, and other factors), dose, dosage form, quantity, route, concentration, rate of administration, or instructions for use of a drug product ordered or authorized by physician (or other legitimate prescriber); illegible prescriptions or medication orders that lead to errors that reach the patient
Omission error ^b	The failure to administer an ordered dose to a patient before the next scheduled dose, if any
Wrong time error	Administration of medication outside a predefined time interval from its scheduled administration time (this interval should be established by each individual health care facility)
Unauthorized drug error ^c	Administration to the patient of medication not authorized by a legitimate prescriber for the patient
Improper dose error ^d	Administration to the patient of a dose that is greater than or less than the amount ordered by the prescriber or administration of duplicate doses to the patient, i.e., one or more dosage units in addition to those that were ordered
Wrong dosage-form error ^e	Administration to the patient of a drug product in a different dosage form than ordered by the prescriber
Wrong drug-preparation error ^f	Drug product incorrectly formulated or manipulated before administration
Wrong administration-technique error ^g	Inappropriate procedure or improper technique in the administration of a drug
Deteriorated drug error ^h	Administration of a drug that has expired or for which the physical or chemical dosage-form integrity has been compromised
Monitoring error	Failure to review a prescribed regimen for appropriateness and detection of problems, or failure to use appropriate clinical or laboratory data for adequate assessment of patient response to prescribed therapy
Compliance error	Inappropriate patient behavior regarding adherence to a prescribed medication regimen
Other medication error	Any medication error that does not fall into one of the above predefined categories

^a The categories may not be mutually exclusive because of the multidisciplinary and multifactorial nature of medication errors.

^b Assumes no prescribing error. Excluded would be (1) a patient's refusal to take the medication or (2) a decision not to administer the dose because of recognized contraindications. If an explanation for the omission is apparent (e.g., patient was away from nursing unit for tests or medication was not available), that reason should be documented in the appropriate records.

^c This would include, for example, a wrong drug, a dose given to the wrong patient, unordered drugs, and doses given outside a stated set of clinical guidelines or protocols.

^d Excluded would be (1) allowable deviations based on preset ranges established by individual health care organizations in consideration of measuring devices routinely provided to those who administer drugs to patients (e.g., not administering a dose based on a patient's measured temperature or blood glucose level) or other factors such as conversion of doses expressed in the apothecary system to the metric system and (2) topical dosage forms for which medication orders are not expressed quantitatively.

^e Excluded would be accepted protocols (established by the pharmacy and therapeutics committee or its equivalent) that authorize pharmacists to dispense alternate dosage forms for patients with special needs (e.g., liquid formulations for patients with nasogastric tubes or those who have difficulty swallowing), as allowed by state regulations.

^f This would include, for example, incorrect dilution or reconstitution, mixing drugs that are physically or chemically incompatible, and inadequate product packaging.

^g This would include doses administered (1) via the wrong route (different from the route prescribed), (2) via the correct route but at the wrong site (e.g., left eye instead of right), and (3) at the wrong rate of administration.

^h This would include, for example, administration of expired drugs and improperly stored drugs.

multiple checks in the medication-use system.

Recommendations for preventing medication errors

Organizational systems for ordering, dispensing, and administering medications should be designed to minimize error. Medication errors may involve process breakdowns in more than one aspect of a system. This section provides recommendations to the management staff (general and departmental) of hospitals, as well as to individual prescribers, pharmacists, nurses, patients, pharmaceutical manufacturers, and others.

Organizational and departmental recommendations. Organizational policies and procedures should be established to prevent medication errors. Development of the policies and procedures should involve multiple departments, including pharmacy, medicine, nursing, risk management, legal counsel, and organizational administration. The following recommendations are offered for organizational management and clinical staff. ^{3A,11-14,16,19-29}

1. Using the principles of the formulary system, the P&T committee (or its equivalent)—composed of pharmacists, physicians, nurses, and other health professionals—should be responsible for formulating policies regarding the evaluation, selection, and therapeutic use of drugs in organized health care settings.
2. Care and consideration must be given in hiring and assigning personnel involved in medication ordering, preparation, dispensing, administration, and patient education. Policies and procedures should be developed that ensure adequate personnel selection, training, supervision, and evaluation. This would include the need to ensure proper interviewing, orientation, evaluation of competency, supervision, and opportunities for continuing professional and technical education.
3. Sufficient personnel must be available to perform tasks adequately. Policies and procedures should ensure that reasonable workload levels and working hours are established and rarely exceeded.
4. Suitable work environments should exist for the preparation of drug products. Potential error sources within the work environment, such as frequent interruptions, should be identified and minimized.
5. Lines of authority and areas of responsibility within the hospital should be clearly defined for medication ordering, dispensing, and administration. The system should ensure adequate written and oral communications among personnel involved in the medication-use process to optimize therapeutic appropriateness and to enable medications to be prescribed, dispensed, and administered in a timely fashion. All systems should provide for review and verification of the prescriber's original order (except in emergency situations) before a drug product is dispensed by a pharmacist. Any necessary clarifications or changes in a medication order must be resolved with the prescriber before a medication is

administered to the patient. Written documentation of such consultations should be made in the patient's medical record or other appropriate record. Nursing staff should be informed of any changes made in the medication order. Changes required to correct incorrect orders should be regarded as potential errors, assuming the changes occurred in time to prevent the error reaching the patient.

6. There should be an ongoing, systematic program of quality improvement and peer review with respect to the safe use of medications. A formal drug-use evaluation (DUE) program, developed and conducted through collaborative efforts among medicine, pharmacy, and nursing, should be integrated and coordinated with the overall hospital quality improvement program. To prevent medication errors, a portion of the DUE program should focus on monitoring the appropriate use of any drugs associated with a high frequency of adverse events, including specific drug classes (such as antimicrobials, antineoplastic agents, cardiovascular drugs) and injectable dosage forms (e.g., potassium products, narcotic substances, heparin, lidocaine, procainamide, magnesium sulfate, and insulin). The quality improvement program should include a system for monitoring, reviewing, and reporting medication errors to assist in identifying and eliminating causes of errors (system breakdowns) and preventing their recurrence. Table 2 lists common causes of medication errors, i.e., areas where there may be system breakdowns.
7. Pharmacists and others responsible for processing drug orders should have routine access to appropriate clinical information about patients (including medication, allergy, and hypersensitivity profiles; diagnoses; pregnancy status; and laboratory values) to help evaluate the appropriateness of medication orders.
8. Pharmacists should maintain medication profiles for all patients, both inpatients and ambulatory patients, who receive care at the hospital. This profile should include adequate information to allow monitoring of medication histories, allergies, diagnoses, potential drug interactions and adverse drug reac-

Table 2.
Common Causes of Medication Errors

Ambiguous strength designation on labels or in packaging
Drug product nomenclature (look-alike or sound-alike names, use of lettered or numbered prefixes and suffixes in drug names)
Equipment failure or malfunction
Illegible handwriting
Improper transcription
Inaccurate dosage calculation
Inadequately trained personnel
Inappropriate abbreviations used in prescribing
Labeling errors
Excessive workload
Lapses in individual performance
Medication unavailable

- tions, duplicate drug therapies, pertinent laboratory data, and other information.
9. The pharmacy department must be responsible for the procurement, distribution, and control of all drugs used within the organization. Adequate hours for the provision of pharmaceutical services must be maintained; 24-hour pharmaceutical service is strongly recommended in hospital settings. In the absence of 24-hour pharmaceutical service, access to a limited supply of medications should be available to authorized nonpharmacists for use in initiating urgent medication orders. The list of medications to be supplied and the policies and procedures to be used (including subsequent review of all activity by a pharmacist) should be developed by the P&T committee (or its equivalent). Items should be chosen with safety in mind, limiting wherever possible medications, quantities, dosage forms, and container sizes that might endanger patients. The use of well-designed night cabinets, after-hours drug carts, and other methods would preclude the need for nonpharmacists to enter the pharmacy. Access to the pharmacy by nonpharmacists (e.g., nurses) for removal of doses is strongly discouraged; this practice should be minimized and eliminated to the fullest extent possible. When 24-hour pharmacy service is not feasible, a pharmacist must be available on an "on-call" basis.
 10. The pharmacy manager (or designee), with the assistance of the P&T committee (or its equivalent) and the department of nursing, should develop comprehensive policies and procedures that provide for the efficient and safe distribution of all medications and related supplies to patients. For safety, the recommended method of drug distribution within the organized health care setting is the unit dose drug distribution and control system.
 11. Except in emergency situations, all sterile and non-sterile drug products should be dispensed from the pharmacy department for individual patients. The storage of nonemergency floor stock medications on the nursing units or in patient-care areas should be minimized. Particular caution should be exercised with respect to drug products that have commonly been involved in serious medication errors or whose margin of safety is narrow, such as concentrated forms of drug products that are intended to be diluted into larger volumes (e.g., concentrated lidocaine and potassium chloride for injection concentrate). All drug storage areas should be routinely inspected by pharmacy personnel to ensure adequate product integrity and appropriate packaging, labeling, and storage. It is important that drug products and other products for external use be stored separately from drug products for internal use.
 12. The pharmacy director and staff must ensure that all drug products used in the organizational setting are of high quality and integrity. This would include, for example, (1) selecting multisource products supported by adequate bioavailability data and adequate product packaging and labeling, (2) maintaining an unexpired product inventory, and (3) keeping abreast of compendial requirements.
 13. The use of a patient's own or "home" medications should be avoided to the fullest extent possible. Use of such medications should be allowed only if there is a need for the patient to receive the therapy, the drug product is not obtainable by the pharmacy, and no alternative therapy can be prescribed. If such medications are used, the prescribing physician must write an appropriate order in the patient's medical record. Before use, a pharmacist should inspect and identify the medication. If there are any unresolved questions with respect to product identity or integrity, the medication must not be used.
 14. All discontinued or unused drugs should be returned to the department of pharmacy immediately upon discontinuation or at patient discharge. Discharged patients must not be given unlabeled drug products to take home, unless they are labeled for outpatient use by the pharmacy in accordance with state and federal regulations. Discharged patients should be counseled about the use of any medications to be used after discharge.
 15. It is recommended that there be computerized pharmacy systems in place that enable automated checking for doses, duplicate therapies, allergies, drug interactions, and other aspects of use. Where possible, the use of technological innovations such as bar coding is recommended to help identify patients, products, and care providers. Pharmacy-generated medication-administration records or labels are recommended to assist nurses in interpreting and documenting medication activities.
 16. Adequate drug information resources should be available for all health care providers involved in the drug-use process.
 17. Standard drug administration times should be established for the hospital by the P&T committee (or its equivalent), with input from the departments of nursing and pharmacy. Policies and procedures should allow for deviations from the standard times when necessary. Further, standard drug concentrations and dosage charts should be developed to minimize the need for dosage calculations by staff.
 18. The P&T committee (or its equivalent) should develop a list of standard abbreviations approved for use in medication ordering. There should be efforts to prohibit or discourage the use of other abbreviations in medication ordering.
 19. A review mechanism should be established through the P&T committee specifying those responsible for data collection and evaluation of medication-error reports. The review group should investigate causes of errors and develop programs for decreasing their occurrence. The review group should be composed of representatives from pharmacy, nursing, medicine, quality assurance, staff education, risk management, and legal counsel.
 20. The pharmacy department, in conjunction with nursing, risk management, and the medical staff, should conduct ongoing educational programs to discuss medication errors, their causes, and methods to prevent their occurrence. Such programs might involve seminars, newsletters, or other methods of information dissemination.

Recommendations for prescribers. Prescribing is an early point at which medication errors can arise. It has been estimated that 1% of hospitalized patients suffer adverse events as the result of medical mismanagement³⁰ and that drug-related complications are the most common type of adverse event.⁷ The following recommendations for preventing medication errors are suggested for physicians and other prescribers.^{3,7,11-16,31}

1. To determine appropriate drug therapy, prescribers should stay abreast of the current state of knowledge through literature review, consultation with pharmacists, consultation with other physicians, participation in continuing professional education programs, and other means. It is especially crucial to seek information when prescribing for conditions and diseases not typically experienced in the prescriber's practice.
2. Prescribers should evaluate the patient's total status and review all existing drug therapy before prescribing new or additional medications to ascertain possible antagonistic or complementary drug interactions. To evaluate and optimize patient response to prescribed drug therapy, appropriate monitoring of clinical signs and symptoms and of relevant laboratory data is necessary.
3. In hospitals, prescribers should be familiar with the medication-ordering system (e.g., the formulary system, participation in DUE programs, allowable delegation of authority, procedures to alert nurses and others to new drug orders that need to be processed, standard medication administration times, and approved abbreviations).
4. Drug orders should be complete. They should include patient name, generic drug name, trademarked name (if a specific product is required), route and site of administration, dosage form, dose, strength, quantity, frequency of administration, and prescriber's name. In some cases, a dilution, rate, and time of administration should be specified. The desired therapeutic outcome for each drug should be expressed when the drug is prescribed. Prescribers should review all drug orders for accuracy and legibility immediately after they have prescribed them.
5. Care should be taken to ensure that the intent of medication orders is clear and unambiguous. Prescribers should
 - a. Write out instructions rather than using non-standard or ambiguous abbreviations. For example, write "daily" rather than "q.d.," which could be misinterpreted as q.i.d. (which would cause a drug to be given four times a day instead of once) or as o.d. (for right eye).
 - b. Do not use vague instructions, such as "take as directed," because specific instructions can help differentiate among intended drugs.
 - c. Specify exact dosage strengths (such as milligrams) rather than dosage form units (such as one tablet or one vial). An exception would be combination drug products, for which the number of dosage form units should be specified.
- d. Prescribe by standard nomenclature, using the drug's generic name (United States Adopted Name, or USAN), official name, or trademarked name (if deemed medically necessary). Avoid the following: locally coined names (e.g., Dr. Doe's syrup); chemical names (e.g., 6-mercaptopurine [instead of mercaptopurine]) could result in a six-fold overdose if misinterpreted; unestablished abbreviated drug names (e.g., "AZT" could stand for zidovudine, azathioprine, or aztreonam); acronyms; and apothecary or chemical symbols.
- e. A leading zero should always precede a decimal expression of less than one (e.g., 0.5 mL). Conversely, a terminal zero should never be used (e.g., 5.0 mL), since failure to see the decimal could result in a 10-fold overdose. When possible, avoid the use of decimals (e.g., prescribe 500 mg instead of 0.5 g).
- f. Spell out the word "units" (e.g., 10 units regular insulin) rather than writing "u," which could be misinterpreted as a zero.
- g. Use the metric system.
6. Written drug or prescription orders (including signatures) should be legible. Prescribers with poor handwriting should print or type medication or prescription orders if direct order entry capabilities for computerized systems are unavailable. A handwritten order should be completely readable (not merely recognizable through familiarity). An illegible handwritten order should be regarded as a potential error. If it leads to an error of occurrence (that is, the error actually reaches the patient), it should be regarded as a prescribing error.
7. Verbal drug or prescription orders (that is, orders that are orally communicated) should be reserved only for those situations in which it is impossible or impractical for the prescriber to write the order or enter it in the computer. The prescriber should dictate verbal orders slowly, clearly, and articulately to avoid confusion. Special caution is urged in the prescribing of drug dosages in the teens (e.g., a 15-meq dose of potassium chloride could be misheard as a 50-meq dose). The order should be read back to the prescriber by the recipient (i.e., the nurse or pharmacist, according to institutional policies). When read back, the drug name should be spelled to the prescriber and, when directions are repeated, no abbreviations should be used (e.g., say "three times daily" rather than "t.i.d."). A written copy of the verbal order should be placed in the patient's medical record and later confirmed by the prescriber in accordance with applicable state regulations and hospital policies.
8. When possible, drugs should be prescribed for administration by the oral route, rather than by injection.
9. When possible, the prescriber should talk with the patient or caregiver to explain the medication prescribed and any special precautions or observations that might be indicated, including any allergic or hypersensitivity reactions that might occur.
10. Prescribers should follow up and periodically evaluate

are the need for continued drug therapy for individual patients.

11. Instructions with respect to "hold" orders for medications should be clear.

Recommendations for pharmacists. The pharmacist is expected to play a pivotal role in preventing medication misuse. The value of pharmacists' interventions to prevent medication errors that would have resulted from inappropriate prescribing has been documented.^{7,22,33} Ideally, the pharmacist should collaborate with the prescriber in developing, implementing, and monitoring a therapeutic plan to produce defined therapeutic outcomes for the patient.¹ It is also vital that the pharmacist devote careful attention to dispensing processes to ensure that errors are not introduced at that point in the medication process. The following recommendations are suggested for pharmacists.^{3,4,8,10,14,16,18,20,23,29}

1. Pharmacists should participate in drug therapy monitoring (including the following, when indicated: the assessment of therapeutic appropriateness, medication administration appropriateness, and possible duplicate therapies; review for possible interactions; and evaluation of pertinent clinical and laboratory data) and DUE activities to help achieve safe, effective, and rational use of drugs.
2. In order to recommend and recognize appropriate drug therapy, pharmacists should stay abreast of the current state of knowledge through familiarity with literature, consultation with colleagues and other health care providers, participation in continuing professional education programs, and other means.
3. Pharmacists should make themselves available to prescribers and nurses to offer information and advice about therapeutic drug regimens and the correct use of medications.
4. Pharmacists should be familiar with the medication-ordering system and drug distribution policies and procedures established for the organizational setting to provide for the safe distribution of all medications and related supplies to inpatients and ambulatory patients. In particular, pharmacists should be familiar with all elements that are designed into the system to prevent or detect errors. Actions by any staff that would (even unintentionally) defeat or compromise those elements should serve as "alerts" to the pharmacist that safety may be affected. Any necessary follow up action (e.g., education or re-education of staff) should ensue promptly. Policies and procedures to be followed for "hold" orders should be clear and understood by pharmacy, medical, and nursing staffs.
5. Pharmacists should never assume or guess the intent of confusing medication orders. If there are any questions, the prescriber should be contacted prior to dispensing.
6. When preparing drugs, pharmacists should maintain orderliness and cleanliness in the work area and perform one procedure at a time with as few interruptions as possible.
7. Before dispensing a medication In nonemergency

situations, the pharmacist should review an original copy of the written medication order. The pharmacist should ensure that all work performed by supportive personnel or through the use of automated devices is checked by manual or technological means. All processes must conform with applicable state and federal laws and regulations. Pharmacists should participate in, at a minimum, a self-checking process in reading prescriptions, labeling (drug or ingredients and pharmacist-generated labeling), and dosage calculations. For high-risk drug products, when possible, all work should be checked by a second individual (preferably, another pharmacist). Pharmacists must make certain that the following are accurate: drug, labeling, packaging, quantity, dose, and instructions.

8. Pharmacists should dispense medications in ready-to-administer dosage forms whenever possible. The unit dose system is strongly recommended as the preferred method of drug distribution. The need for nurses to manipulate drugs (e.g., measure, repack, and calculate) prior to their administration should be minimized.
9. Pharmacists should review the use of auxiliary labels and use the labels prudently when it is clear that such use may prevent errors (e.g., "shake well," "for external use only," "not for injection").
10. Pharmacists should ensure that medications are delivered to the patient-care area in a timely fashion after receipt of orders, according to hospital policies and procedures. If medication doses are not delivered or if therapy is delayed for any reason pending resolution of a detected problem (e.g., allergy or contraindications), the pharmacist should notify the nursing staff of the delay and the reason.
11. Pharmacists should observe how medications are actually being used in patient-care areas to ensure that dispensing and storage procedures are followed and to assist nurses in optimizing patient safety.
12. Pharmacy staff should review medications that are returned to the department. Such review processes may reveal system breakdowns or problems that resulted in medication errors (e.g., omitted doses, unauthorized drugs).
13. When dispensing medications to ambulatory patients (e.g., at discharge), pharmacists should counsel patients or caregivers and verify that they understand why a medication was prescribed and dispensed, its intended use, any special precautions that might be observed, and other needed information. For inpatients, pharmacists should make their services available to counsel patients, families, or other caregivers when appropriate.
14. Pharmacists should preview and provide advice on the content and design of preprinted medication-order forms or sheets, if these are used.
15. Pharmacists should maintain records sufficient to enable identification of patients receiving an erroneous product.

Recommendations for nurses. By virtue of their direct patient-care activities and administration of medications to patients, nurses—perhaps more than any

other health care providers—are in an excellent position to detect and report medication errors. Nurses often serve as the final point in the checks-and-balances triad (physicians and other prescribers, pharmacists, and nurses) for the medication-use process; thus, they play an important role in risk reduction. The following recommendations for preventing medication administration errors are suggested.^{3,14,16,17,34}

1. Nurses who practice in organized health care settings should be familiar with the medication-ordering and use system (e.g., participation in DUE activities, order processing, and standard medication administration times).
2. Nurses should review patients' medications with respect to desired patient outcomes, therapeutic duplications, and possible drug interactions. Adequate drug information (including information on medication administration and product compatibilities) should be obtained from pharmacists, nurses, other health care providers, the literature, and other means when there are questions. There should be appropriate follow-up communication with the prescriber when this is indicated.
3. All drug orders should be verified before medication administration. Nurses should carefully review original medication orders before administration of the first dose and compare these with medications dispensed. Transcriptions of orders should be avoided to the extent possible and should be recognized as prime opportunities for errors. Doses should not be administered unless the meaning of the original order is clear and unambiguous and there are no questions with respect to the correctness of the prescribed regimen. Nurses should check the identity and integrity (e.g., expiration date, general appearance) of the medications dispensed before administering them. When there are discrepancies, the nurse should contact the pharmacy department and determine the appropriate action.
4. Patient identity should be verified before the administration of each prescribed dose. When appropriate, the patient should be observed after administration of the drug product to ensure that the doses were administered as prescribed and have the intended effect.
5. All doses should be administered at scheduled times unless there are questions or problems to be resolved. Medication doses should not be removed from packaging or labeling until immediately before administration. The administration of medication should be documented as soon as it is completed.
6. When standard drug concentrations or dosage charts are not available, dosage calculations, flow rates, and other mathematical calculations should be checked by a second individual (e.g., another nurse or a pharmacist).
7. The drug distribution system should not be circumvented by "borrowing" medications from one patient (or another hospital area) to give to a different patient or by stockpiling unused medications. If there are apparent missing doses, it is important

that the pharmacy be contacted for explanation or correction. There may be an important reason why the dose was not sent to the patient-care area (e.g., allergy, contraindication, questionable dose), and resolution of the potential question or problem may be pending.

8. If there are questions when a large volume or number of dosage units (e.g., more than two tablets, capsules, vials, or ampuls) is needed for a single patient dose, the medication order should be verified. Consult with the pharmacist and prescriber as appropriate.
9. All personnel using medication-administration devices (e.g., infusion pumps) should understand their operation and the opportunities for error that might occur with the use of such devices.
10. Nurses should talk with patients or caregivers to ascertain that they understand the use of their medications and any special precautions or observations that might be indicated. Any counseling needed should be provided before the first dose is administered, when possible.
11. When a patient objects to or questions whether a particular drug should be administered, the nurse should listen, answer questions, and (if appropriate) double check the medication order and product dispensed before administering it to ensure that no preventable error is made (e.g., wrong patient, wrong route, dose already administered). If a patient refuses to take a prescribed medication, that decision should be documented in the appropriate patient records.

Recommendations for patients and personal caregivers. Patients (or their authorized caregivers or designees) have the right to know about all aspects of their care, including drug therapy. When patient status allows, health care providers should encourage patients to take an active role in their drug use by questioning and learning about their treatment regimens. Generally, if patients are more knowledgeable, anxieties about the uncertainty of treatments can be alleviated and errors in treatment may be prevented. The following suggestions are offered to help patients whose health status allows, and their caregivers, make the best use of medications.¹

1. Patients should inform appropriate direct health care providers (e.g., physicians, nurses, pharmacists) about all known symptoms, allergies, sensitivities, and current medication use. Patients should communicate their actual self-medication practices, even if it differs from the prescribed directions.
2. Patients should feel free to ask questions about any procedures and treatments received.
3. Patients should learn the names of the drug products that are prescribed and administered to them, as well as dosage strengths and schedules. It is suggested that patients keep a personal list of all drug therapy, including prescribed drugs, nonprescription drugs, home remedies, and medical foods. Patients should also maintain lists of medications that they cannot take and the reasons why. This infor-

mation should be shared with health care providers. Patients should be assertive in communicating with health care providers when anything seems incorrect or different from the norm.

4. After counseling from an authorized health care provider about the appropriateness of the medication, patients should take all medications as directed.

Recommendations for pharmaceutical manufacturers and approval organizations. Poor designs with respect to drug product packaging and labeling, as well as selection of inappropriate or confusing nomenclature, have been identified as factors that contribute to serious medication errors by practitioners.^{4,35-37} Pharmaceutical manufacturers and approval agencies should be responsive to efforts of practitioners to minimize errors. The following guidelines are recommended for the pharmaceutical industry and regulatory authorities.^{3,4,10,38}

1. Drug manufacturers and the Food and Drug Administration (FDA) are urged to involve pharmacists, nurses, and physicians in decisions about drug names, labeling, and packaging.
2. Look-alike or sound-alike trademarked names and generic names should be avoided.
3. Similar proprietary appearances of packaging and labeling should be avoided, because look-alike products contribute to medication errors.
4. The use of lettered or numbered prefixes and suffixes in trademarked names is generally discouraged. Lettered prefixes or suffixes could be mistaken for instructions or strength. Commonly used medical abbreviations should never be used in trademarked names (e.g., "HS" could stand for half-strength or a bedtime dose). Numbers as part of trademarked names could be mistaken for quantities to be administered. Coined abbreviations that could misinterpreted (e.g., MTX, U, HCTZ) should not be used in trademarked names.
5. Special instructions should be highlighted on labeling, such as the need for dilution before administration.
6. The most prominent items on the product label should be information in the best interest of safety (e.g., product name and strength). Less prominence should be given to company names or logos.
7. Drug manufacturers are encouraged to make dosage forms available commercially in unit dose and unit-dosing containers, as well as bulk packaging, to facilitate their appropriate use in all practice settings.
8. Drug manufacturers must communicate with health care providers (i.e., pharmacists, physicians, and nurses) when changes are made in product formulations or dosage forms.

Monitoring and managing medication errors

Monitoring medication errors. Ongoing quality improvement programs for monitoring medication errors are needed. The difficulty in detecting errors has long been recognized as one of the barriers to effectively studying

the problem.³⁹ Medication errors should be identified and documented and their causes studied in order to develop systems that minimize recurrence.^{3,4,7,10,11,14,16,22,40} Several error-monitoring techniques exist (e.g., anonymous self-reports, incident reports, critical-incident technique, disguised-observation technique) and may be applied as appropriate to determine the rates of errors.^{9,40,41} There are differences in the validity of data obtained by the various error-monitoring techniques or combined techniques. Program managers should determine the best method for use in their organizations in consideration of utility, feasibility, and cost. Monitoring programs for medication errors should consider the following risk factors^{6,10,11,22,40-41}:

1. Work shift (higher error rates typically occur during the day shift).
2. Inexperienced and inadequately trained staff.
3. Medical service (e.g., special needs for certain patient populations, including geriatrics, pediatrics, and oncology).
4. Increased number or quantity of medications per patient.
5. Environmental factors (lighting, noise, frequent interruptions).
6. Staff workload and fatigue.
7. Poor communication among health care providers.
8. Dosage form (e.g., injectable drugs are associated with more serious errors).
9. Type of distribution system (unit dose distribution is preferred; floor stock should be minimized).
10. Improper drug storage.
11. Extent of measurements or calculations required.
12. Confusing drug product nomenclature, packaging, or labeling.
13. Drug category (e.g., antimicrobials).
14. Poor handwriting.
15. Verbal (orally communicated) orders.
16. Lack of effective policies and procedures.
17. Poorly functioning oversight committees.

Managing medication errors. Medication errors result from problematic processes, but the outcomes of medication errors could range from minimal (or no) patient risk to life-threatening risk. Classification of the potential seriousness and clinical significance of detected medication errors should be based on predefined criteria established by the P&T committee (or its equivalent). The error classification should be based on the original order, standard medication dispensing and administration procedures, dosage forms available, acceptable deviation ranges, the potential for adverse consequences and patient harm, and other factors.^{6,22,41}

Classification of medication errors should allow for better management of follow-up activities upon medication error detection. A simple classification of medication errors is the following: (1) clinically significant (includes potentially fatal or severe, potentially serious, and potentially significant errors) or (2) minor.^{7,23} Hartwig, Denger, and Schneider defined seven medication-error severity levels, as follows⁴¹:

Level 0—No medication error occurred (potential errors would be classified here).

Level 1—An error occurred that did not result in patient harm.

Level 2—An error occurred that resulted in the need for increased patient monitoring but no change in vital signs and no patient harm.

Level 3—An error occurred that resulted in the need for increased patient monitoring with a change in vital signs but no ultimate patient harm, or any error that resulted in the need for increased laboratory monitoring.

Level 4—An error occurred that resulted in the need for treatment with another drug or an increased length of stay or that affected patient participation in an investigational drug study.⁴

Level 5—An error occurred that resulted in permanent patient harm.

Level 6—An error occurred that resulted in patient death.

Medication error classifications could also be based on probability and severity scales analogous to those used in adverse drug reaction reporting programs.^{42,43}

Determination of the causes of medication errors should be coupled with assessment of the severity of the error. While quality management processes should include programs to decrease the incidence of all medication errors, effort should be concentrated on eliminating the causes of errors associated with greater levels of severity. There should be established mechanisms for tracking drugs or drug classes that are involved in medication errors. Correlations between errors and the method of drug distribution should also be reviewed (e.g., unit dose, floor stock, or bulk medications; premixed or extemporaneously compounded products; oral or injectable products). These processes will help identify system problems and stimulate changes to minimize the recurrence of errors.

Quality improvement programs should provide guidance for patient support, staff counseling and education, and risk management processes when a medication error is detected. Incident-reporting policies and procedures and appropriate counseling, education, and intervention programs should be established in all hospitals. Risk management processes for medication errors should include pharmacists, physicians, and nurses, in addition to risk management specialists, legal counsel, and others as appropriate. The following actions are recommended upon error detection.^{3,7,10,11,16,17,27,43}

1. Provide any necessary corrective and supportive therapy to the patient.
2. Document and report the error immediately after discovery, in accordance with written procedures. For clinically significant errors, an immediate oral notice should be provided to physicians, nurses, and pharmacy managers. A written medication error report should follow promptly.
3. For clinically significant errors, fact gathering and investigation should be initiated immediately. Facts that should be determined and documented in-

clude what happened, where the incident occurred, why the incident occurred, how the incident occurred, and who was involved. Appropriate product evidence (e.g., packaging, labeling) should be retrieved and retained for future reference until causative factors are eliminated or resolved.

4. Reports of clinically significant errors and the associated corrective activities should be reviewed by the supervisor and department head of the area(s) involved, the appropriate organizational administrator, the organizational safety committee (or its equivalent), and legal counsel (as appropriate).
5. When appropriate, the supervisor and the staff members who were involved in the error should confer on how the error occurred and how its recurrence can be prevented. Medication errors often result from problems in systems, rather than exclusively from staff performance or environmental factors^{2,44,45}; thus, error reports should not be used for punitive purposes but to achieve correction or change.
6. Information gained from medication error reports and other means that demonstrates continued failure of individual professionals to avoid preventable medication errors should serve as an effective management and educational tool in staff development, or if necessary, modification of job functions or staff disciplinary action.
7. Supervisors, department managers, and appropriate committees should periodically review error reports and determine causes of errors and develop actions to prevent their recurrence (e.g., conduct organizational staff education, alter staff levels, revise policies and procedures, or change facilities, equipment, or supplies).
8. Medication errors should be reported to a national monitoring program so that the shared experiences of pharmacists, nurses, physicians, and patients can contribute to improved patient safety and to the development of valuable educational services for the prevention of future errors. Reports of medication errors can be made by telephone to the United States Pharmacopeial Convention, Inc. (USP) Medication Errors Reporting Program (1-800-23ERROR). Reports can be submitted to USP on a confidential basis if the reporter so chooses. Other reporting programs may also be in existence or under development. Reporting programs are intended to track trends and inform practitioners, regulators, and the pharmaceutical industry of potential product and system hazards that have a documented association with medication errors.

⁴⁴The mention of investigational drugs in the definition of level 4 errors (and nowhere else in the levels) may lead some to believe that any error involving an investigational drug should automatically be classified as a level 4 error. However, in discussing this issue at its September 1992 meeting, the ASHP Council on Professional Affairs noted that it is the effect on the patient (for a medication of any type) that really should determine what level of error is involved.

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Chairman STARK [presiding]. Mr. Ellis, does the American Society of Hospital Pharmacists oppose the mandatory requirement in Mr. Coyne's bill?

Mr. ELLIS. The way the bill is currently structured, we do.

Chairman STARK. That is not what I asked. Do you oppose the mandatory requirement for reporting?

Mr. ELLIS. Yes.

Chairman STARK. Well, there is no sense in dealing with you. You are outranked. Dr. Woosley says that it is—without the—the voluntary nature of MedWatch will limit its potential, and he thinks that the requirement, the mandatory requirement, for reporting is essential.

Why are you the only guys who do not like it? What have you got against it? Are you scared?

Mr. ELLIS. Well, we feel that practitioners will be more open to voluntary—

Chairman STARK. But it has not worked so far.

Mr. ELLIS. I think the USP-ISMP program has put together a pretty impressive track record in terms of—

Chairman STARK. But it has only hit 1 percent. You guys have not done it.

Now come on. What scares you about 'fessing up and making this mandatory? Is it just that you do not like laws, or are you hiding something?

Mr. ELLIS. No, I do not think that health care professionals are hiding anything. We are really looking at an outcome-based—

Chairman STARK. Then they ought not to object to mandatory reporting, should they?

Mr. ELLIS. Well, we need to see some proof that mandatory reporting programs really do increase compliance.

Chairman STARK. Well, we have got the proof that voluntary is not working. So why do we not try the other thing? You are a scientist, are you not?

Mr. ELLIS. A pharmacist.

Chairman STARK. Yes. Do you not believe in experimenting and getting data and trying new things?

Mr. ELLIS. Well, I think we do need to take a look at certain parts of programs to see whether they work or whether they do not work.

The bottom line, though, is focusing on the outcomes, and that is the prevention of medication errors.

Chairman STARK. Look, the whole thing today is, are we going to make this a law or are we not? And why are you guys—what I want to know is, what are you afraid of? Why can we not make this a law? It would get it done.

Mr. ELLIS. And we have some concerns about how the program would be implemented at the Federal level, what the role of the FDA would be, and that is—

Chairman STARK. I understand that there are a lot of people who do not like the FDA. There are a lot of people who do not like Medicare. A lot of my colleagues would do away with Medicare and Medicaid; do you know that? Really. Make it voluntary.

Are you for that? Would your group support making Medicare voluntary?

Mr. ELLIS. Well, that is not the purpose of our—

Chairman STARK. Well, I know. But, I mean, for example, would you make licensing of pharmacists voluntary?

Mr. ELLIS. I think—

Chairman STARK. Now wait 1 minute. Would you make licensing of pharmacists voluntary?

Mr. ELLIS. No.

Chairman STARK. I can count—I can get to 20 with my shoes and socks off. I can dispense pills. Should I be allowed to dispense pills?

Mr. ELLIS. Well, with all due respect, there is a lot more that goes into the profession of pharmacy than—

Chairman STARK. OK. Well, maybe there is a lot more that goes into reporting than just passing out little cards and saying: Sign up if you choose.

Mr. ELLIS. Well, reporting systems, whether they be voluntary or whether they be mandatory, when they are designed, need to be very comprehensive, need to involve a lot of practitioners, because as we talked about in the testimony, the answers—

Chairman STARK. Well, let us get back to it. What is wrong with requiring people to do this? What do you think they will do? If we pass Mr. Coyne's law, what will happen?

Mr. ELLIS. Well, I think the fear that we have—

Chairman STARK. I do not want to talk about fears. Come on. What—give me an example of what would happen. Why would I or my family be at risk if the FDA collects this information, and it is mandatorily required to be reported?

Mr. ELLIS. You and your family would be at risk if the program does not address outcomes.

Chairman STARK. Wait 1 minute.

Mr. ELLIS. And in the mere collection of data, the mandatory—

Chairman STARK. Look, we are just talking about whether it is going to be a voluntary—whether this is the United Crusade or the Internal Revenue Service, all right? And I will tell you, the Internal Revenue Service collects a hell of a lot more money than the United Crusade. And people cheat a lot less than what they say they are putting in the church plate. Believe it.

Now regardless of how you want to use this information or how you want to categorize it, none of which I am sure that I am competent to understand, the only question that seems to be—we are arguing about here is: Do I require people associated with providing medical care and pharmaceutical procedures to report under a certain format, which we would love to have you participate in and help us write?

It is very difficult, I might remind you, to deal with people who say no. There is nothing to negotiate with you. When you say no, we will leave you out, and we will take the three gentlemen to your right, who are interested in doing this and helping us write Mr. Coyne's law.

What I am trying to get at, is that I understand people who do not like government. There are days, believe it or not, when I do not like it, you know? When we are going to invade Haiti, I do not like government.

But what is there besides the fact that you somehow think—and that is all I can determine—that volunteerism is better than a mandate, now why?

Mr. ELLIS. The FDA themselves have stated regarding the MedWatch program that they just feel that there will be higher compliance with that. When people fear that there are punitive measures that are going to be taken, they are reluctant to report it, whether it is mandatory or not mandatory. And that we feel voluntary programs offer that option for people to do that without that threat. And that is realistic.

Chairman STARK. So you think that people who are scared to have the information divulged, because it might reflect badly on them, would be more apt to 'fess up if it was voluntary than if it was mandatory?

Mr. ELLIS. Well, we would have to study side-by-side, you know, programs.

Chairman STARK. So I would say to you, if you give somebody the wrong pills, and it is voluntary, then you just do not get your gold star for the week. If it is mandatory, you go to jail.

Now when you think about that, when you go home tonight and say, am I going to come back and really confess, missing the gold star or going to the Ivan Bosky tennis ranch for 6 months, which is more apt to get you to tell the truth?

Mr. ELLIS. Well, I do not know that, you know, we really—our goals are any different. Our goals are to improve the system and to improve public safety. We have taken a look at—

Chairman STARK. I will stipulate that, Mr. Ellis. Look, you are an honorable, upright member of your profession.

I am just saying I cannot get into focus this mandatory issue. There is something troubling people, and it may very well just be that—say it—just a philosophic difference, that they do not think government should be involved. I have heard that about FDA. We do not really have much jurisdiction over FDA.

So our good colleague, Mr. Waxman, hears us all the time, and I hear it from these crumbs at the Pharmaceutical Manufacturers Association, the worst people in this country. They do not want the FDA to do anything. They would kill everybody for a nickel, if they had their way. So they would say: Make it voluntary. There is no way you would let those clowns unleash their poison on the public without having it tested first.

Now why?

Mr. ELLIS. I think there is also a system in place that has a record of results, and that is another reason: Why reinvent the wheel if there is a system or a program out there?

Chairman STARK. So you are going to hang it on—your argument is: It is working now; do not change it?

Mr. ELLIS. I think that we need to give that program adequate time to prove that there is a problem with that before—

Chairman STARK. When you get to be my age, Mr. Ellis, you do not have that much time. I am going to have to take that stuff that you prescribe pretty soon, and I do not want to wait. So I want you to get this thing in place. We cannot wait. These youngsters to my right can wait. But I have got to have it soon.

Now how am I going to get you to do—

Mr. COYNE. I am not going to get from 1 percent to 90 percent. I am done. I will yield to Mr. Lewis.

Mr. LEWIS. Mr. Chairman, I cannot wait. I am your age, you know, so I cannot wait.

Mr. ELLIS, I really do not understand—I really do not have a question, but I do not understand the problem with a mandatory system, mandates.

You know, mandates have been around for a long time. It is not something that is new. Mandates are as old as the Scriptures. When God gave Moses the Ten Commandments, he did not say: Moses, you can take them if you want to. He did not say: If you feel like it. Just do it. You know, go and do it.

Social Security is a mandate. We have a lot of mandates in this country. So to provide for the health care of our people, why not a mandatory program? The present system is not working. I think you told the chairman—what is it—1 percent or less?

Chairman STARK. That is what I keep hearing, yes.

Mr. ELLIS. Let me rephrase, then, the position. If we are going to create a mandatory system, then let us make sure that the system is complementary and comprehensive and—

Chairman STARK. Now you are talking! Welcome to the club! Now, you are at the table, Mr. Ellis.

Mr. ELLIS. Well, but it is also important to understand that volume and numbers of reports does not equate to anything.

Chairman STARK. We are with you. Now you can sit down with Mr. Coyne here and get to work with the other three gentlemen at the table and Mr. Coyne and work out a system.

They are all yours, Mr. Coyne. [Laughter.]

Mr. COYNE. Dr. Perper, you had indicated that this might be a system that would involve both the Federal and State governments.

Do you think that the State government boards, who would be responsible for collecting information, would be willing to work with the Federal Government? Is that your sense, in your experience?

Dr. PERPER. I was until very recently the chairman of the State Board of Pennsylvania for a number of years, so I am very familiar with the operation of the board, and the board had certainly a very definite interest in detecting medical errors and making sure that they do not reoccur.

But because the question was of mandatory versus voluntary, and I heard during the first panel the suggestion that if there is a mandate, there should be a mandate of reporting death rather than serious injury.

I just want to bring to the attention of the panel that such legal mandates exist in every community in this country, because if a death results from a medication, from the administration of medication or in terms of procedure or in terms of dose or in terms of error, this is an unnatural death, which under the law which is currently in force, is reportable to the coroner or medical examiner.

And let me tell you that in my experience as a medical examiner, I saw that over the years, as my interest in detecting medical misadventure increased, the number of medical misadventures re-

ported which led to death increased from 2 to 20 over a period of about 10 years.

So therefore there is no argument for discussion, and therefore if there is mandatory reporting, it should address serious injury as well.

As for the reason, providers of care do not intend to bring about death or injury to their patients. They do that either because of ignorance or because of error or because they do not have the knowledge or they are tired.

And the reason why they do not report, it is not a secret. This affects their professional reputation, damages their professional competence, and they are human as much as anybody else. So they do not feel any great urge to report an injury which is going to hurt them substantially unless they are forced to do that.

And that is: In my opinion, a provision or a law, a statute, which would not have mandatory reporting would be a statute which would not have any effective teeth or force to perform what it wants to do, which means better medical care for Americans.

Thank you.

Mr. COYNE. I would like to ask Dr. Woosley and Dr. Perper, AARP's testimony noted that some elderly take several medications prescribed by different physicians.

What would be the difference between a negative drug interaction and a medication error? Is there a difference in meaning there?

Dr. WOOSLEY. I think if I understand your question correctly, there is a difference in one sense, a practical difference. But as far as its importance, I think they are both important, and both should be reported and categorized and analyzed to make sure we know which we are talking about.

A medication error again, as was pointed out earlier, is a very complex event that has to be analyzed. A drug interaction, though, is something that can be anticipated in most cases if we have the data and are aware of the data, and then we have the physician educated in how to prevent that interaction from happening. In many cases a computer at some point and a pharmacist can identify and prevent those interactions.

But I think they are very different, but both important. And I think they both need to be reported.

One of the most serious problems we have today is that we do not know how big the problem is. We know it is a problem, and until we know how big the problem is, we will not know if what we are doing about it works or not. We have got all these programs that we have heard about today that are trying to solve the problem, but we cannot prove that they are effective, because we do not know how big the problem was before these programs started.

The FDA actually has data that the number of drug-induced deaths has not changed a bit over the last 10 years. So maybe these efforts are not helping. We do not really know.

And that is what this bill will do. It will give us better data. It will not be perfect, but it will at least tell us how bad the problem is, and then we can start attacking it.

Dr. PERPER. I think we are back to the problem of definition, and I think that there is some confusion about the definition of terms.

An adverse medical result may be preventable or unpreventable. If it is preventable, it may be a result of medical error, or it may not be a result of medical error. It may have something to do with the drug or the reaction of the particular patient.

And then even in the deaths which are due to error, there is a subdivision between an error which is a nonnegligent error and an error which is a negligent error, because in order to be negligent, it has to fall below the standard of accepted medical care.

I disagree, with all respect, with the premise that you cannot make a determination of medical errors. In many cases, the ones which end in death, the determination in most cases is very clear. Somebody gives an excessive dose of medication; the wrong person gets the medication; an instrument is not disconnected and diffuses all kinds of toxic substances.

So this is really not a problem. I think that the problem, as I said, is that the statute has to have a mandatory provision, and the mandatory provision would permit the dissemination of information, which I think the bill of Congressman Coyne wants to achieve.

Dr. WOOSLEY. Could I elaborate on this last point?

Mr. COYNE. Sure.

Dr. WOOSLEY. Because I think it is an important one, and I do not think we disagree. I think you are right, that there are many examples where deaths due to drugs are very clear.

But there are many examples where they are not, and we are losing that in our current system. A very good example is that people were being killed by antihistamines, Seldane, for 10 years, and nobody knew it. And it is very clear now in retrospect. But for 10 years, doctors were saying: My gosh, I am sorry that allergy patient died; I wonder what it was. It sure could not have been this safe antihistamine that I gave him.

So we do not know the problem, because we do not have the data. And that is what we really need. We need more data.

You are right. It is very easy when somebody takes an overdose or somebody writes the wrong prescription, but that is just the tip of the iceberg.

Dr. LIONE. The point I was making on the interaction of medications was that we have such a volume of medications out there; the PDR gets thicker and thicker every year. And unless we know if there is any interaction, we do not have that information. We need to be able to have some network to get that information and communicate it to the practitioners who are prescribing these medications.

In addition to that, there are so many over-the-counter medications that patients may be taking that we need to know about how they may interact.

So it is a very complex situation with the volume of medications we have, that we want to be able to use effectively. And we need to know as providers and physicians if there is some harmful effect. And we do take that oath not to do harm. But if there is a harmful effect, and I am not aware of it, how can I prevent that from happening, and I need to share that with the other practitioners.

Dr. PERPER. Incidentally, most of the fatal therapeutic misadventures and therapeutic misadventures in general affect the Amer-

ican people above 60, and above 64 are the ones who are suffering most of those incidents.

And I think there are a number of things in terms of medication which act at cross ends. There are so many of them that most physicians are not able to remember them. And usually when you need this kind of memory helper, probably some kind of computer program in offices might detect those kinds of dangerous situations.

Mr. ELLIS. It is important to reiterate—and I think we are all on the same page here—though, that we can get into a lot of different issues regarding medication errors and adverse reactions and drug interactions, and they all really are very separate. So I think we have to be careful, too. Although they are all major problems with drug use, we have to be careful to keep those somewhat separated, so that we can address and come up with solutions for each of those.

Chairman STARK. Let me try this. We talked a lot in the ill-fated discussion of health reform about outcomes research. This deals mostly with physicians. And generally the physician community, if they did not think we were going to provide a cookbook for them to tell them how to practice medicine, were in favor of keeping more detailed records of how people were treated and their outcomes, particularly those who lived, but for several years, because you may have to do something today and not die today, but 10 years from now—or you should have lived 15, and you died in 10 years.

And as we pick up that data, we were advised that we would help the people who were trying to train physicians in developing more useful protocols.

I do not think we ever heard the suggestion that that database could be built voluntarily. I do not think even the AMA said that they would oppose the Federal Government participating in that.

Now it would seem to me to be just be a minor extension of that concept of building a database to include pharmaceutical protocols and therapies in the data we collect.

Then you all, who are professionals and can understand this, may very well have a lot of suggestions as to how that data should be used and who should have access to it and what is determined from it. I do not think we have that capability.

But I think we do have the ability to expedite building this database, so that you all, from whatever, whether it is from a voluntary group that decides they want to research it or whether it is the pedagogical side of medicine that thinks they can train people better or whatever, for public health people who want to prevent unnecessary deaths, we are just getting a lot more information.

And what I sense in Mr. Coyne's bill is that that is what he is trying to facilitate. There may be some disagreement or some suggestions as to how this information should be categorized, how it should be stored and disseminated. I think that has to be done by professionals like yourselves.

But what I do not see is, somebody has to say: Let us do it. And basically I think that is what Mr. Coyne has come up with, who has said it is time.

Has not your organization, Mr. Ellis—or two or three, as I understand it—voluntary groups probably working in coordination, certainly not at cross-purposes? There are teaching hospitals and schools of medicine and pharmacology that are trying to collect this information. There are State governments.

And I think what we are saying is: Hey, why do we not get it together and have—build a database, so that when we all have computers, we can then use the information, understanding privacy questions, questions of protecting a person's professional reputation, and not certainly making or divulging information capriciously, which may not—which we may not have sufficient information to act and suggest that somebody did something incorrectly?

I mean, all of those things, I think, can be taken into account. But none of it, it seems to me, can get done unless you start. And I think the gentleman from Pennsylvania has come up with one small piece of this idea of information-gathering that will help us get going.

And I hope we can bring, Mr. Ellis, your group—and there were some others here today who take the same position—into agreement. And once we get it started, I think we should step back and let you all make those decisions—that has certainly has been our practice on this committee—as to the professional details of how best to do it.

Dr. Woosley.

Dr. WOOSLEY. Can I make one additional quick comment?

In my testimony I made the point, and I would like to repeat it, that I think this problem is huge, and there is nothing in our government today or our society—not the pharmaceutical industry, not our medical education system—nothing in government is trying to solve this problem. We already know it exists. This bill will help us quantify it.

But we have got to do more. We have got to do something proactively to get at the problems that our drugs are causing, our prescriptions are causing, and our efforts have got to be multifaceted.

We have got to educate everybody, all the way from doctors to the person who takes the pill or gives the pill.

Mr. COYNE. Go ahead.

Dr. LIONE. Mr. Chairman, may I make one comment?

I think Mr. Lewis earlier with the first panel was asking about educating the consumer. I would like you to know that AARP has been very active with our health advocacy services programs to train volunteers, so that we do go to our members to try to educate them to the proper use of prescription drugs. We have a very active program to explain to them the proper use of medications and when they do get to the health provider, to be prepared to ask questions, get the information they need, so they can intelligently—

Chairman STARK. Pretty good mail-order pharmaceutical service, too, huh, Dr. Lione?

Dr. LIONE. Yes, we do. And we provide an extra service—

Chairman STARK. Get the commercial in; that is all right.

Dr. LIONE [continuing]. To help them get the benefit of quality of medications and look at the cost there, too. Thank you.

Chairman STARK. All right. I just wanted--Mr. Ellis, you can get a commercial in, too, for the hospitals.

Mr. ELLIS. I just wanted to make sure that the subcommittee was clear that, you know, ASHP wants to have the safest system out there for patients, and that is the real bottom line of all that we were talking about today.

We may differ a little bit philosophically on how to get to that point. But I think and hope that the subcommittee understands that we are 100 percent committed to that intent.

Chairman STARK. You hang around here long enough, Mr. Ellis, you will learn to love this subcommittee. You will insist that we make it mandatory, just so you can come back often and chat with us.

Dr. PERPER. I just would like to emphasize again that though this bill is very helpful, that it is addressing only about one-fifth, 20 percent, of the problem of therapeutic misadventure. This is the percentage represented by medication errors.

Thank you.

Chairman STARK. Thank you.

As I say, we have heard a lot about protecting people from capricious malpractice suits.

Now this hearing today is one of the first we have had on protecting me from capricious malpractice. And that is one of the best ways to stop the suits, is it not?

Dr. PERPER. I believe so.

Chairman STARK. If I do not have anything to sue you for, well, everybody is happy.

Dr. PERPER. And the studies have shown that--in the document, the Harvard study on therapeutic misadventure, only 2 percent of true negligent cases went to malpractice suits, which means that all the suits basically which were brought in the State were not thoroughly justified.

Mr. COYNE. Well, I just want to thank Chairman Stark and the members of the subcommittee for agreeing to hold this hearing today, and I think we have gotten a lot of important information in the testimony from the witnesses. I appreciate all of your testimony.

I just had one question for Mr. Ellis. Several of the other witnesses have indicated that if there is a mandatory system, that the reporting be done through a State licensing or practicing board.

Would your organization support that?

Mr. ELLIS. I think we would really have to study the complexities of that. I think we want to make a system that is as direct and as easy for people to participate in and eliminates confusion and also makes sure that when we collect this data, we are comparing apples to apples, so to speak.

Chairman STARK. That it is uniform.

Mr. ELLIS. Yes.

Mr. COYNE. Well, once again, thank you, Mr. Chairman.

Chairman STARK. Dr. Woosley.

Dr. WOOSLEY. That was my point. And that is, I think the most important point is that it must be uniform, perhaps collected at one site. But if we do have 52 different systems, they should get to-

gether and make sure they are all collecting data in the same way. If not, we are going to end up with more questions than answers.

Mr. COYNE. Well, thank you, Mr. Chairman.

Chairman STARK. Thank you, Mr. Coyne.

Mr. COYNE. And Mr. Lewis and members of the panel.

Chairman STARK. I want to thank all the witnesses today. It has been very informative. Thank you.

[Whereupon, at 12:45 p.m., the hearing was adjourned.]

[A submission for the record follows:]

Ensuring the Safety of Medication Administration Protocols *The Hospital Council of Western Pennsylvania*

The Hospital Council of Western Pennsylvania applauds Congressman William Coyne for proposing the Safe Medications Act of 1993. His actions have elevated this critical issue to a national platform that can focus public and professional discussion toward an effective solution.

In practice, however, we strongly urge **the enhancement of existing voluntary medication error report efforts, rather than pursuit of legislative remedy.** Considerations supporting this strategy include:

- **The data already exist through a number of resources and reporting mechanisms, such as FPA MedWatch, at the local, state and federal levels.**

Better coordination and utilization of these voluntary systems will yield a wealth of information, enabling practitioners to track and intervene in practices and protocols that may have an unintended negative affect on patient care.

Refinement of current voluntary processes will avoid adding to the already inflated and expensive health care bureaucracy. Developing a strategy to centralize disparate resources — rather than legislatively creating another agency or layer of bureaucracy — will conserve health care dollars and optimize the speed of gathering and analyzing potentially life-saving data.

- **Disciplinary action already exists through the courts and the insurance system.**

Legislating another layer of investigation and discipline will only slow the process further and expend valuable health care dollars that could be applied to improving patient care.

- **Existing voluntary systems and resources offer the quality of information necessary for real improvement in patient care.**

The complexity of this issue calls for much more than aggregate statistics. Through various reporting mechanisms, health care organizations and professionals provide documentation of the circumstances and systems related to the medication error. This level of data is necessary to accurately identify a trend and to suggest alternative protocols.

Centralizing this existing information will result in a powerful tool to maximize patient benefit.

- **A national review board with appropriate expertise could effectively monitor the process, while ensuring the completeness and accuracy of the data and their analysis.**



Safe Medications Act of 1993
A Response
The Hospital Council of Western Pennsylvania

We commend Congressman William Coyne for raising the issue of medication errors to a national platform that can focus public and professional discussion toward an effective solution. In practice, however, we **strongly recommend the enhancement of existing voluntary medication error report efforts rather than pursuit of legislative remedy.**

As this legislation is developed, we urge consideration of the following revisions:

- **Existing reports generated through local, state and federal systems must be coordinated to incorporate the same processes and information and minimize expensive regulatory bureaucracy.**
- **Real improvement in patient care can only be achieved if the shared information is pertinent and comprehensive.**
The information must offer more than just aggregate statistics. Documentation of the circumstances and systems related to the medication error is necessary to accurately identify a trend and to suggest alternative protocols.
- **A very clear definition of "medication error" must be developed and applied, with distinction being made between contributing versus directly resultant errors.**
The reporting protocol should cover both fatal medication errors and errors resulting in severe morbidity for a more complete picture of a possible trend.
- **To ensure necessary confidentiality of the circumstances surrounding a medication error, the process must be discreet and non-punitive.**
The depth of information required for meaningful trend analysis could breach patient confidentiality should the data be made public. Protecting against incomplete or inappropriate public disclosure will also ensure fairness for both parties engaged in a related lawsuit.
- **The reporting process must be realistic to ensure accuracy and compliance.**
A 30 day reporting period will adequately allow for thorough internal investigation and complete reporting of all circumstances surrounding the medication error.



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